IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

JENNIFER BRIDGES, *et al*	§	
	§	
Plaintiffs,	§	
	§	
V.	§	Civil Action No. 4:21-CV-01774
	§	
THE METHODIST HOSPITAL D/B/A THE METHODIST HOSPITAL SYSTEM, AND HOUSTON METHODIST THE WOODLANDS HOSPITAL,	§	
	§	
Defendants.	§	

DECLARATION OF DR. PETER A. McCULLOUGH, MD, MPH

I, Peter McCullough, hereby declare:

1. I am over 18 years of age, of sound mind, and in all ways capable of making this Declaration. The facts stated in this declaration are within my personal knowledge and are true and correct. I could and would testify competently to these facts if called upon to do so.

2. I submit this Declaration in support of the Bridges Plaintiffs motion for temporary restraining order in Civil Action No. 4:21-CV-01774 in the Southern District of Texas.

3. After receiving a bachelor's degree from Baylor University, I completed my medical degree as an Alpha Omega Alpha graduate from the University of Texas Southwestern Medical School in Dallas. I went on to complete my internal medicine residency at the University of Washington in Seattle, a cardiology fellowship including service as Chief Fellow at William Beaumont Hospital, and a master's degree in public health at the University of Michigan.

4. I am board certified in internal medicine and cardiovascular disease and hold an additional certification in clinical lipidology, and previously echocardiography. I am on the medical staff at Baylor University Medical Center and Baylor Jack and Jane Hamilton Heart and Vascular Hospital, in Dallas, Texas. I am also on staff at Baylor Heart and Vascular Institute, which promotes cardiovascular research and education. I practice internal medicine and clinical cardiology as well as teach, conduct research, and I am an active scholar in medicine with roles as an author, editorialist, and reviewer at dozens of major medical journals and textbooks. I am Professor of Medicine at Texas A & M University School of Medicine, Baylor Dallas Campus.

5. I have led clinical, education, research, and program operations at major academic centers (Henry Ford Hospital, Oakland University William Beaumont School of Medicine) as well as academically oriented community health systems. I spearheaded the clinical development of *in vitro* natriuretic peptide and neutrophil gelatinase associated lipocalin assays in diagnosis, prognosis, and management of heart and kidney disease now used worldwide. I also led the first clinical study demonstrating the relationship between severity of acute kidney injury and mortality after myocardial infarction. I have contributed to the understanding of the epidemiology of chronic heart and kidney disease through many manuscripts from the Kidney Early Evaluation Program Annual Data Report published in the American Journal of Kidney Disease and participated in clinical trial design and execution in cardiorenal applications of acute kidney injury, hypertension, acute coronary syndromes, heart failure, and chronic cardiorenal syndromes. I participated in event adjudication (involved attribution of cause of death) in trials of acute coronary syndromes, chronic kidney disease, heart failure, and data safety and monitoring of anti-diabetic agents, renal therapeutics, hematology products, and gastrointestinal treatments. I have served as the chairman or as a member of over 20 randomized trials of drugs, devices, and clinical strategies. Sponsors have included pharmaceutical manufacturers, biotechnology companies, and the National Institutes of Health.

6. I frequently lecture and advise on internal medicine, nephrology, and cardiology to leading institutions worldwide. I am recognized by my peers for my work on the role of chronic kidney disease as a cardiovascular risk state. I have over 1,000 related scientific publications, including the "Interface between Renal Disease and Cardiovascular Illness" in Braunwald's Heart Disease Textbook. My works have appeared in the New England Journal of Medicine, Journal of the American Medical Association, and other top-tier journals worldwide. I am an associate editor of the American Journal of Cardiology and the American Journal of Kidney Diseases. I have testified before the U.S. Senate Committee on Homeland Security and Governmental Affairs, the U.S. Food and Drug Administration Cardiorenal Advisory Panel and its U.S. Congressional Oversight Committee, and the Texas Senate Committee on Health and Human Services.

7. I am a Fellow of the American College of Cardiology, the American Heart Association, the American College of Physicians, the American College of Chest Physicians, the National Lipid Association, and the National Kidney Foundation. I am also a Diplomate of the American Board of Clinical Lipidology.

8. In 2013, I was honored with the International Vicenza Award for Critical Care Nephrology for my contribution and dedication to the emerging problem of cardiorenal syndromes. I am the President of the Cardiorenal Society of America, an organization dedicated to bringing together cardiologists and nephrologists and engage in research, improved quality of care, and community outreach to patients with both heart and kidney disease.[1]

[1] *See* http://www.cardiorenalsociety.org/.

9. I am the current President of the Cardiorenal Society of America, a professional organization dedicated to advancing research and clinical care for patients who have combined heart and kidney disease. I am the Editor-in-Chief of *Cardiorenal Medicine*, a primary research journal listed by the National Library of Medicine which is the only publication with a primary focus on research concerning patients with combined heart and kidney disease. Finally, I am the Editor-in-Chief of *Reviews in Cardiovascular Medicine*, a widely read journal that publishes reviews on contemporary topics in cardiology and is also listed by the National Library of Medicine.

10. My appended *curriculum vitae* further demonstrates my academic and scientific achievements and provides a list of publications authored by me in the past 30 years.[2]

11. Since the outset of the pandemic, I have been a leader in the medical response to the COVID-19 disaster and have published "Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection," the first synthesis of sequenced multidrug treatment of ambulatory patients infected with SARS-CoV-2 in the *American Journal of Medicine* and updated in *Reviews in Cardiovascular Medicine*.[3] I have 40 peer-reviewed publications on the COVID-19 infection cited in the National Library of Medicine. Through a window to public policymakers, I have contributed extensively on issues surrounding the COVID-19 crisis in a series of OPED's for *The Hill*. I testified on the SARS-CoV-2 outbreak in the U.S. Senate Committee on Homeland Security and Governmental Affairs on November 19, 2020. I testified on lessons learned from the pandemic response in the Texas Senate Committee on Health and Human Services on March 10, 2021, and on early treatment of COVID-19 the Colorado General Assembly on March 31, 2021. Additionally, I testified in the New Hampshire Senate on legislation concerning the investigational COVID-19 vaccine on April 14, 2020. My expertise on the SARS-CoV-2 infection and COVID-19 syndrome, like that of infectious disease specialists, is approximately 18 months old. I have

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[2] Exhibit 1.

[3] McCullough PA, Kelly RJ, Ruocco G, Lerma E, Tumlin J, Wheelan KR, Katz N, Lepor NE, Vijay K, Carter H, Singh B, McCullough SP, Bhambi BK, Palazzuoli A, De Ferrari GM, Milligan GP, Safder T, Tecson KM, Wang DD, McKinnon JE, O'Neill WW, Zervos M, Risch HA. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. Am J Med. 2021 Jan;134(1):16-22. doi: 10.1016/j.amjmed.2020.07.003. Epub 2020 Aug 7. PMID: 32771461; PMCID: PMC7410805 available at https://pubmed.ncbi.nlm.nih.gov/32771461/; McCullough PA, Alexander PE, Armstrong R, Arvinte C, Bain AF, Bartlett RP, Berkowitz RL, Berry AC, Borody TJ, Brewer JH, Brufsky AM, Clarke T, Derwand R, Eck A, Eck J, Eisner RA, Fareed GC, Farella A, Fonseca SNS, Geyer CE Jr, Gonnering RS, Graves KE, Gross KBV, Hazan S, Held KS, Hight HT, Immanuel S, Jacobs MM, Ladapo JA, Lee LH, Littell J, Lozano I, Mangat HS, Marble B, McKinnon JE, Merritt LD, Orient JM, Oskoui R, Pompan DC, Procter BC, Prodromos C, Rajter JC, Rajter JJ, Ram CVS, Rios SS, Risch HA, Robb MJA, Rutherford M, Scholz M, Singleton MM, Tumlin JA, Tyson BM, Urso RG, Victory K, Vliet EL, Wax CM, Wolkoff AG, Wooll V, Zelenko V. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). Rev Cardiovasc Med. 2020 Dec 30;21(4):517-530. doi: 10.31083/j.rcm.2020.04.264. PMID:33387997 available at https://pubmed.ncbi.nlm.nih.gov/33387997/.

formed my opinions based on my direct clinical experience with acute and convalescent COVID-19 cases as well has closely following the preprint and published literature on the outbreak. I have specifically reviewed all the key published rare cases and reports concerning possible recurrence of SARS-CoV-2.

12. Additional details regarding my training and experience are contained in the true and correct copy of my curriculum vitae attached to this Declaration as Exhibit 1.

13. The following statements are based on my years of training, experience, and medical studies. The articles and documents attached are commonly referred to by professionals like myself and I consider them to be authoritative in my field.

14. Of the currently available vaccines for COVID-19 in investigational use in the United States have none have received final full approval from the FDA. Rather, each one of the COVID-19 vaccines is an "unapproved product" that has been granted EUA.[4] The FDA itself refers to the COVID-19 vaccines as "investigational products."

15. The investigational SARS-CoV-2 vaccines manufactured by Pfizer and Moderna contain laboratory synthesized mRNA in a lipid package and theadeno viral DNA in JNJ in viral vector. This mRNA/adeno viral DNA enters the host's cells and takes over the cells causing them to produce the Wuhan spike protein which elicits the development of antibodies.[5] The Wuhan spike protein, independent of the SARS-CoV-2 virion, has been demonstrated to be pathogenic or damaging to blood vessels, organs (brain, heart, lungs, liver, bone borrow) and to be directly thrombogenic by causing hemagglutination and thrombosis. The human host cells respond to the Wuhan spike protein and elicit cell signaling otherwise known as inflammation.[6] The Wuhan spike protein is produced in an uncontrolled fashion without limits on duration. The mRNA/adeno viral DNA vaccines may also affect the host cells which may result in cellular dysfunction and death.[7] Researchers in the cited study recommend that the long-term consequences be monitored carefully for these experimental vaccines, especially when they are administered to otherwise healthy individuals.[8] Scientists further conclude that further investigations on the effects of the SARS-CoV-2 spike protein on human cells and appropriate experimental animal models are warranted.[9]As a medical

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[4] Exhibit 2.

[5] Exhibit 3: Suzuki YJ, Gychka SG. SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Host Cells: Implications for Possible Consequences of COVID-19 Vaccines. *Vaccines (Basel).* 2021;9(1):36. Published 2021 Jan 11. doi:10.3390/vaccines9010036.

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Id.* ("However, we need to consider their long-term consequences carefully, especially when they are administered to otherwise healthy individuals as well as young adults and children. In addition to evaluating data that will become available from SARS-CoV-2 infected individuals as well as those who received the spike protein-based vaccines, further investigations of the effects of the SARS-CoV-2 spike protein in human cells and appropriate animal models are warranted.")

researcher and practitioner, this study, and others credibly informs me that these mRNA/adeno viral DNA vaccines are not safe for their intended use.

16. The trials relied upon for EUA by the FDA excluded large groups because of lack of expected efficacy and safety concerns. These groups included: COVID-19 recovered, suspected COVID-19 recovered, those with positive COVID-19 serologies, pregnant women, and women of childbearing age who could not ensure contraception. Since these groups were excluded for the trials, the EUA vaccines should not be administered since good clinical practice (GCP) never encourages use of untested, unproven, and potentially unsafe products in excluded groups from randomized registrational trials.

17. The fact that the safety of these vaccines is questionable is not controversial. For example, a consent form from a respected medical institution states, "There is limited information known about the safety and effectiveness of using this vaccine."[10] It goes on, "The Moderna COVID-10 Vaccine is still being studied in clinical trials."

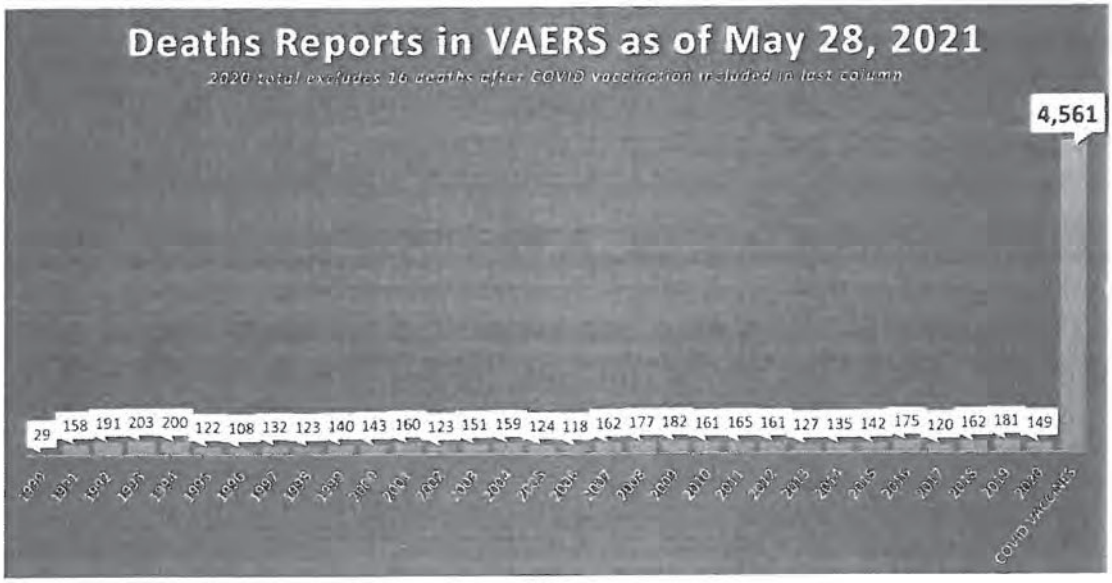
18. Thus, far, there are no prospective randomized double-blind placebo controlled randomized trials demonstrating clinical benefit, i.e., reductions in COVID-19 hospitalization and death. There are calls into the FDA advising not to approve the EUA COVID-19 vaccines for clinical use (Citizen Petition Urges FDA Against Premature Full Approval of Covid Vaccines Many open, unanswered questions surrounding the efficacy and safety of COVID-19 vaccines must be answered before the FDA considers granting a full approval, https://www.regulations.gov/document/FDA-2021-P-0521-0001).

19. The current COVID-19 vaccines are not sufficiently protective against contracting COVID-19 to support its use beyond the current voluntary participation in the CDC sponsored program. A total of 10,262 SARS-CoV-2 vaccine breakthrough infections had been reported from 46 U.S. states and territories as of April 30, 2021. Among these cases, 6,446 (63%) occurred in females, and the median patient age was 58 years (interquartile range = 40–74 years). Based on preliminary data, 2,725 (27%) vaccine breakthrough infections were asymptomatic, 995 (10%) patients were known to be hospitalized, and 160 (2%) patients died. Among the 995 hospitalized patients, 289 (29%) were asymptomatic or hospitalized for a reason unrelated to COVID-19. The median age of patients who died was 82 years (interquartile range = 71–89 years); 28 (18%) decedents were asymptomatic or died from a cause unrelated to COVID-19. Sequence data were available from 555 (5%) reported cases, 356 (64%) of which were identified as SARS-CoV-2 variants of concern, including B.1.1.7 (199; 56%), B.1.429 (88; 25%), B.1.427 (28; 8%), P.1 (28; 8%), and B.1.351 (13; 4%). None of these variants are encoded in the RNA or DNA of the current COVID-19 vaccines. In response to these numerous reports, the CDC announced on May 1, 2021, that community breakthrough cases would no longer be reported to the public and only those vaccine failure cases requiring hospitalization will be reported, presumably on the CDC website (https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm)

[10] Exhibit 4 – Baylor Scott & White Health Consent Form.

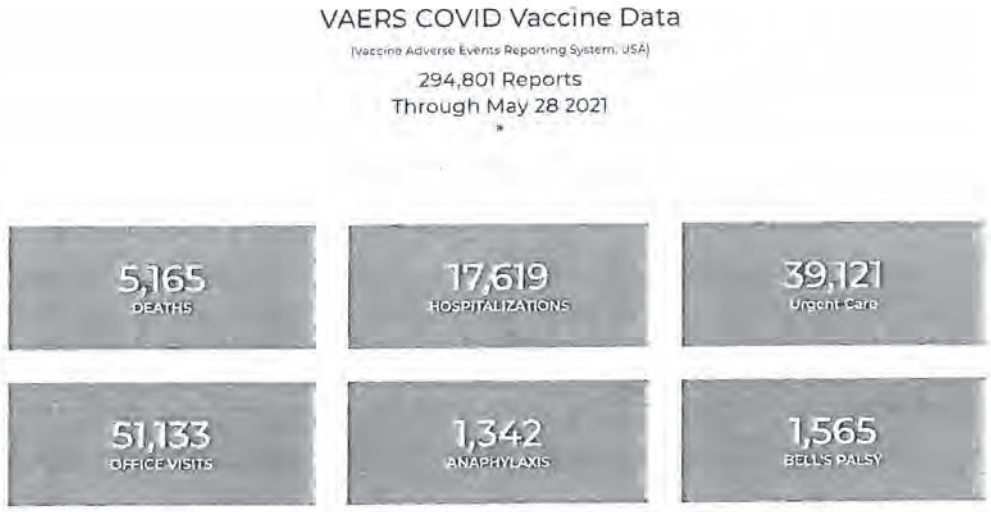
20. In 1990, the Vaccine Adverse Event Reporting Systems ("VAERS") was established as a national early warning system to detect possible safety problems in U.S. licensed vaccines.[11] VAERS is a passive reporting system, meaning it relies on individuals to voluntarily send in reports of their experiences to CDC and FDA. VAERS is useful in detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine.

21. Based on VAERS as of May 28, 2021, there were 5,165 deaths reported and over 17,619 hospitalizations reported. By comparison, from July 1, 1997, until December 31, 2013, VAERS received 666 adult death reports for all vaccines.[12] Following is a graphical representation of VAERS data:



[11]VAERS may be publicly accessed at https://www.openvaers.com/covid-data.

[12] Exhibit 5. Pedro L. Moro, Jorge Arana, Mria Cano, Paige Lewis, and Tom T. Shimabukuro, Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997-2013, VACCINES, CID 2015:61 (September 2015).



22. Flu vaccines are linked to 20–30 death reports a year, and those 20–30 death reports come with considerably more vaccines administered. Arguably, if the experimental vaccine was any other vaccine or drug, it would already have been removed from the market. Usually, a new drug is withdrawn after 50 deaths, which is not typical because the FDA has a strict approval process. By comparison, the Swine Flu mass vaccine program in 1976 vaccinated 55 million of the nation's 220 million inhabitants and resulted in 500 cases of Gullian Barre syndrome and 25 total deaths and was withdrawn from use in what was reported to be a public health debacle.

23. With the current COVID-19 vaccines in EUA use since December 2020, a reported 5,165 deaths represents over 100 times the normal threshold for pulling a drug from the market. Although this is raw data, previous VAERS studies have shown that only 1-10% of vaccine-related deaths are reported to VAERS —or less.[13] The COVID vaccines are adding a year's worth of VAERS death reports every week. In just five months, more adverse reports were added to the VAERS database than any single vaccine has had cumulatively over the past 31 years. It is also interesting to note that 46% of deaths are estimated to occur 1-3 days after receipt of the first injection.

24. With approximately 50% of the US population vaccinated, mortality is not the only serious adverse event that has been reported after the COVID-19 vaccine largely by physicians and healthcare workers who are concerned the clinical event is related to the investigational COVID-19 vaccine. Additional morbidity reported to the CDC and verified with a permanent VAERS number include: 17,619 HOSPITALIZATIONS, 39,121 Urgent Care visits, 51,133 OFFICE VISITS, 1,342 cases of ANAPHYLAXIS, 1,565 cases of BELL'S PALSY, 5,317 Life Threatening events, 1,892 Heart Attacks, 756 cases of Myocarditis/Pericarditis, 1,392 cases

[13] https://www.openvaers.com/covid-data.

of Thrombocytopenia/Low Platelet, 571 Miscarriages, 13,574 Severe Allergic Reactions, 3,994 Disabling illnesses.[14]

25. The lack of safety of the COVID-19 vaccines is worldwide issue and a group of 57 authors from 17 countries has published a call for immediate risk mitigation with CEC, DSMB and IRB independent committees, otherwise halt the world wide programs. (https://www.authorea.com/users/414448/articles/522499-sars-cov-2-mass-vaccination-urgent-questions-on-vaccine-safety-that-demand-answers-from-international-health-agencies-regulatory-authorities-governments-and-vaccine-developers).

26. An important issue with the vaccines that is being ignored in the vaccine-enthused medical community is whether those people who have already contracted and recovered from SARS-COV-2 should receive the mRNA/adeno viral DNA vaccines. There are 3 published studies on this matter. [15] The conclusion is that for those with previous SARS-COV-2 a mRNA/adeno viral DNA is contraindicated and harmful since there is no opportunity for benefit and only an opportunity for harm. There are no published studies to the contrary, i.e., that the mRNA/adeno viral DNA vaccines are safe to take by those who have already had SARS-COV-2.

27. Raw et al. reported that in 974 individuals who received the BNT162b2/Pfizer vaccine, those with a prior history of SARS-CoV-2 or those who had positive antibodies at baseline, had a higher rate of vaccine reactions than those who were COVID-19 naive.[16]

28. Mathioudakis et al. reported that in 2002 patients who underwent vaccination with either mRNA-based, or vector-based COVID-19 vaccines, COVID-recovered patients who were needlessly vaccinated had higher rates of vaccine reactions.[17]

29. Krammer et al. reported on 231 volunteers for COVID-19 vaccination, 83 of whom had positive SARS-CoV-2 antibodies at the time of immunization. The authors found: "Vaccine recipients with preexisting immunity experience systemic side effects with a significantly higher frequency than antibody naïve vaccines (e.g., fatigue, headache, chills, fever, muscle or join pains, in order of decreasing frequency, $P < 0.001$ for all listed symptoms, Fisher's exact test, two-sided)." (https://doi.org/10.1101/2021.01.29.21250653).

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[14] https://www.openvaers.com/covid-data.

[15] Florian Krammer, Komal Srivastava, the PARIS team, and Viviana Simon, Robust Spike Antibody Responses and Increased Reactogenicity in Seropositive Individuals After a Single Does of SARS-COV-2 mRNA Vaccine, Feb. 1, 2021; Alexander G. Mathioudakis, Murad Ghrew, Andrew Ustianowski, Shazaad Ahmad, Ray Borrow, Lisa Pieretta Papavasileiou, Dimitrios Petrakis, Nawar Diar Bakerly, Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: An International Vaccine-Recipient Survey, March 8, 2021; Rachel K. Raw, Clive Kelly, Jon Rees, Caroline Wroe, and David R. Chadwick, Previous COVID-19 Infection by not Long-COVID is Associated with Increased Adverse Events Following BNT162b2/Pfizer Vaccination, April 22, 2021.

[16] *See* https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1.

[17] *See* https://www.medrxiv.org/content/10.1101/2021.02.26.21252096v1.

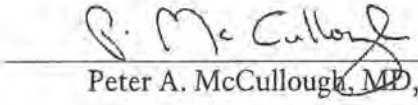
30. To my knowledge, there are no studies demonstrating clinical benefit of COVID-19 vaccination in COVID-19 survivors or those who have laboratory evidence of prior infection.

31. It is my opinion that SARS-CoV-2 causes an infection in humans that results in robust, complete, and durable immunity, and is superior to vaccine immunity. There are no studies demonstrating clinical benefit of COVID-19 vaccination in COVID-19 survivors and there are three studies demonstrating harm in such individuals. Thus, it is my opinion that the COVID-19 vaccination is contraindicated in COVID-19 survivors.

32. Overall, based on my 30 years in medicine, and in reviewing thousands of medical studies and abstracts, this is dangerous and uncharted territory in the medical field. Never before has an employer required an EUA product under clinical investigation without proven efficacy and safety, in a program without protection of human research subjects (EAC, DSMB, IRB). Participation in research is always voluntary and according to the Office of Human Research Protections and the Nuremberg Code, must be free of pressure, coercion (including offering money), and threat of reprisal (e.g. termination of employment). It is my opinion as a physician and active healthcare worker, there is no scientific or clinical support for any employer to mandate the participation of a clinical investigation of any COVID-19 vaccine(s) products as a condition of employment. The vaccines are not sufficiently protective, have not been shown to be clinically beneficial meaning no COVID-19 reduction in hospitalization and death, and have been found to have an unfavorable safety profile with unacceptably high rates of serious safety events including hospitalization and death after injection. No persons should be effectively forced into clinical research where the well-known possibility of serious adverse effects including death could occur as a result of being coerced against their will and right of autonomy over what is injected into their bodies.

33. I declare under penalty of perjury that the foregoing is true and correct.

EXECUTED on June 9, 2021



June 9, 2021

Peter A. McCullough, MD, MPH

13-APR-2021

Thursday, April 8, 2021

CURRICULUM VITAE

PETER A. McCULLOUGH, MD, MPH, FACP, FACC, FCCP, FAHA, FNKF, FNLA, FCRSA

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5231 Richard Avenue
Dallas, TX 75206

Birth date December 29, 1962
Birthplace Buffalo, NY, USA

EDUCATION

1) Certificate of Graduate Liberal Arts Studies: Southern Methodist University, December 17, 2016, principal faculty Dr. Anthony Picchioni, PhD, Adjunct Professor in Human Development, P.O. Box 750181, Dallas, TX 75275, 214-768-3417, www.smu.edu
   - Graduated with Honor

2) Master of Public Health: University of Michigan School of Public Health, August 19, 1994, Dean Noreen M. Clark, PhD, 109 Observatory Street, Ann Arbor, MI 48109-2029, phone 734-764-5454, www.sph.umich.edu
   - Major: General Epidemiology

3) Doctor of Medicine: University of Texas Southwestern Medical School, June 4, 1988, Dean Bryan M. Williams, MD, 5323 Harry Hines Boulevard, Dallas, TX 75235-9070, 214-648-3111, http://www.utsouthwestern.edu/education/medical-school/
   - Clinical year rank of 1 in 199, overall rank in class of 12 in 199
   - Alpha Omega Alpha Texas Gamma Chapter, installed March 17, 1988

4) Bachelor of Science: Baylor University, May 18, 1984, Chancellor Abner McCall, PhD, Office of the Registrar, Waco, TX 76798-7056, 254-710-1181, http://www.baylor.edu/
   - Double-major: Biology and Psychology
   - Graduated with Honor, degree rank of 29 in 131, university rank of 127 in 1,152

EXHIBIT
1-1

- Alpha Lambda Delta Freshman Honorary, installed March 19, 1981

POSTGRADUATE TRAINING

1) Cardiovascular Diseases Fellowship: William Beaumont Hospital (WBH) (presently Oakland University William Beaumont School of Medicine), Division of Cardiology, 3601 W. Thirteen Mile Rd, Royal Oak, MI 48073, 248-551-4198, 7-1-94 to 6-30-97, Chief Cardiovascular Fellow for 1996-97, William W. O'Neill, MD, Program Director and Division Chief

2) Internal Medicine Residency: University of Washington School of Medicine, Department of Internal Medicine, 1959 NE Pacific, Seattle, WA 98195, (206) 543-3239, 3-year traditional track, 7-1-88 to 6-30-91, James F. Wallace, MD, Program Director, Paul G. Ramsey, MD, Chairman of Medicine

PROFESSIONAL EXPERIENCE

HeartPlace Baylor Dallas Campus, Texas A & M University College of Medicine, Baylor Dallas Campus, 3409 Worth Street, Suite 500, Dallas TX 75246, March 1, 2021 to present.

Positions Held: 1) Professor of Medicine, Department of Internal Medicine, Texas A & M University College of Medicine
2)Attending Physician

Baylor Scott and White Health, Baylor Health Care System, Baylor University Medical Center (BUMC), Baylor Heart and Vascular Institute, Baylor Jack and Jane Hamilton Heart and Vascular Hospital, Dallas TX, Texas A & M University College of Medicine, Department of Medicine, Division of Cardiology, Baylor Heart and Vascular Institute, 621 N. Hall St., #H030, Dallas, TX 75226, February 3, 2014 to February 25, 2021. Cardiovascular Governance Council, Kevin Wheelan, MD, Cardiology Division Chief and Chief Medical Officer, Heart Institute Office (214) 820-7500

Positions Held: 1) Professor in the Principal Faculty, Non-Tenure Track in the Department of Internal Medicine, Texas A & M University Health Sciences Center
2) Chief of Cardiovascular Research
3) Program Director, BUMC Cardiovascular Diseases Fellowship Program
4) Vice Chief, BUMC Internal Medicine

St. John Providence Health System, Providence Park Heart Institute, Department of Medicine, Cardiology Section, 47601 Grand River Avenue, Suite B-125, Novi, MI 48374, September 1, 2010 to July 19, 2013. Department of Medicine Chair, Anibal Drelichman, MD: 248-849-3152, Cardiology Section Chief: Shukri David, MD, 248-465-5955

Positions Held: 1) Chief Academic and Scientific Officer (Academic Dean Equivalent), St. John Providence Health System, (2010 to 2013)

2) Medical Director, Clinical Lipidology, Department of Medicine, Cardiology Section (2010 to 2013)

William Beaumont Hospital, Department of Internal Medicine, Divisions of Nutrition and Preventive Medicine, Department of Cardiology, 3601 West Thirteen Mile Road, Royal Oak, MI 48073, October 1, 2002 to 2010. Department of Medicine Chair: Michael A. Maddens, M.D., 248-551-0622, Department of Cardiology Chair: David E. Haines, M.D., 248-858-0404

Oakland University William Beaumont School of Medicine, 472 O'Dowd Hall 2200 N. Squirrel, Rochester, MI 48309, Robert Folberg, MD, Medical School Dean, Kenneth Hightower, PhD, Dean of Allied Health Sciences, 248-370-3562. Clinical Professor of Health Sciences and Medicine (2007 to 2010)

Positions Held:
1) Consultant Cardiologist and Chief, Division of Nutrition and Preventive Medicine (2002 to 2010), Department of Internal Medicine
2) Medical Director, Preventive Cardiology (2002 to 2010)
3) Medical Director, Lipid Apheresis Program (2007 to 2010)
4) Medical Director, Weight Control Center (2002-2005)

University of Missouri-Kansas City (UMKC) School of Medicine, Truman Medical Center, Department of Medicine, Cardiology Section, 2301 Holmes St., Kansas City, MO 64108. August 18, 2000-September 30, 2002. Department of Medicine Chair: George R. Reisz, M.D, 816-556-3450

Positions Held:
1) Associate Professor of Medicine (Tenure Track) and Cardiology Section Chief

Henry Ford Health System (HFHS), Henry Ford Heart and Vascular Institute, 2799 W. Grand Blvd., K-14, Detroit, MI 48202, July 1, 1997 to August 16, 2000. Cardiovascular Division Head: W. Douglas Weaver, M.D, 800-653-6568

Positions Held:
1) Assistant Professor of Medicine (Tenure Track), Case Western Reserve University School of Medicine, and HFHVI Senior Staff Cardiologist
Medical Director, Preventive Cardiology, 1999-2000
2) Program Director, Cardiovascular Diseases Fellowship Training Program, 1999-2000
3) Director of Cardiovascular Informatics Section, 1997-2000
4) Associate Director of the Center for Clinical Effectiveness, 1997-99
5) Associate Director of the Cardiovascular Diseases Fellowship Program, 1998-99

Emergency Physicians Medical Group, PC, 2000 Green Road, Suite 300, Ann Arbor, MI 48105, 800-466-3764. Emergency medicine attending at Mission Health McPherson Hospital, Howell,

1991-1997; Oakwood Beyer Hospital Center, Ypsilanti 1991-1997, and Mercy Hospital, Grayling 1991-1992

Positions Held: 1) Associate Member
2) Washtenaw County Human Services Deputy Medical Examiner, 1995-1996

Mercy Internal Medicine Associates, 308 Michigan Avenue, Grayling, MI 49738, Mercy Hospital-Grayling, 1100 Michigan Avenue, Grayling, MI 49738, 517-348-5461. Internal medicine attending at Mercy Hospital, Grayling, MI, 1991-1992

Positions Held: 1) Coronary Care Unit Director
2) Physician Director of Cardiopulmonary Services

SPECIAL TRAINING

1) The Healthcare Forum Cardiovascular Health Fellowship, 1998-99
2) American Heart Association (AHA), 23rd 10-Day U.S. Seminar on the Epidemiology and Prevention of Cardiovascular Disease, July-August, 1997
3) University of Michigan Summer Session in Epidemiology, 1997-99
4) Stanford University Course on Medical Informatics, Palo Alto, CA, June, 1997
5) Current Practice of Vascular Ultrasound 3-Day Course, Chicago, IL, April, 1997
6) Advanced Pacemaker Concepts Course, CPI, Inc., Lansing, MI, 1995
7) Pacesetter Comprehensive Pacemaker 4-Day Course, Santa Fe, NM, 1997
8) Medtronic Bakken Education Tutorial and Medtronic Applied Physiological Research Laboratory Lead Implantation Training and Biventricular Implantation Training (2 sessions), Minneapolis, MN, 2001-2002
9) 2004 ASCeXAM Review Course, American Society of Echocardiography, San Francisco, CA, April 22-24, 2004
10) National Lipid Association Masters Course in Clinical Lipidology, Hilton Head, SC, August 21-23, 2008

CERTIFICATION AND LICENSURE

1) Licensed in the State of Washington 1988-1997 (#MD00027562), Michigan expires January 31, 2022 (#4301058147), and New York 1992 to present (#189283 inactive status), Missouri 2000-2002 (#2000165365 inactive status) and Texas expires May 31, 2022 (#P9222)
2) FLEX passed April 4, 1990, State of Washington, Department of Health, Board of Medical Examiners
3) Diplomate, American Board of Internal Medicine, Candidate #136084, September, 25, 1991, recertified May 1, 2001, valid through 2011, recertified June 10, 2011, valid through 2021, 510 Walnut Street, Suite 1700, Philadelphia, PA 19106-3699
4) Diplomate, American Board of Internal Medicine, Cardiovascular Diseases Subspecialty, Candidate #136084, November, 1997, valid through 2007, recertified October 1, 2007, valid

through 2017, recertified September 28, 2017, valid through 2027, 510 Walnut Street, Suite 1700, Philadelphia, PA 19106-3699

5) Diplomate, American Board of Clinical Lipidology, September 27, 2008, 6816 Southpoint Parkway, Suite 1000, Jacksonville, FL 32216. Fellow, National Lipid Association
6) National Board of Echocardiography (NBE), Examination of Special Competence in Adult Echocardiography, 2004-2014 expired
7) Diplomate, American Board of Forensic Examiners, July 16, 1996, no expiration date

RECOGNITION

Teaching:

1. Henry Ford Hospital, 1999 Chief Medical Resident's Best Teacher Award

Research:

1. Chest Foundation Young Investigator Award 2001, Philadelphia, PA, November 7, 2001, President's International Awards Ceremony

2. National Kidney Foundation (NKF) of Michigan, Innovations in Health Care Award Finalist 2008, East Lansing, MI, April 17, 2008

3. American College of Cardiology (ACC) Simon Dack Award for Scholarly Excellence by the Journal of the American College of Cardiology, March 5, 2009

4. 11th International Vicenza Award in Critical Care Nephrology, International Renal Research Institute, Vicenza, Italy, June 11, 2013

Postgraduate:

1. Founding Fellow, Cardiorenal Society of America, March 2016
2. Fellow, National Lipid Association, January, 2013
3. Fellow, National Kidney Foundation, January, 2012
4. Fellow, American College of Chest Physicians, February, 2001
5. Fellow, American College of Physicians, January, 2001
6. Fellow, American College of Cardiology, February, 1999

AFFILIATIONS

1) Alpha Omega Alpha, National Honor Medical Society, 1988 to present
2) American College of Emergency Physicians, Member, 1992-1994
3) American College of Forensic Examiners, Member 1996 to present
4) AHA, Council on Epidemiology and Prevention, 1995 to present
5) AHA, Grassroots Network, 1998-2000.
6) Central Society for Clinical Research, Member, 1999-2000
7) Council on Geriatric Cardiology, Member 1996-1997
8) Michigan Chapter of the ACC, Chair, Annual Cardiology Board Review, 1999-2000

9) Michigan State Medical Society, Member, 1997-2000, 2004 to 2009
10) The American Medical Informatics Association, 1997-2000
11) The Health Forum, Charter Cardiovascular Health Charter Alumni Representative, 1998 to 2002
12) Cardiorenal Society of America, Founding Executive Board Member, 2013 to present, Vice President 2014-2016, President 2016 to present
13) Dallas County Medical Society, 2014 to present
14) Texas Medical Association, 2014 to present
15) Baylor Alumni Association, 2015 to present
16) New York Academy of Sciences, 2016 to present

EDITORIAL RESPONSIBILITIES

1) *Advances in Chronic Kidney Disease,* Editorial Board Member, 2003-present. [referenced through Elsevier Bibliographic Database, EMBASE/Excerpta Medica, MEDLINE]
2) *American Journal of Cardiology,* Associate Editor, 2014 to present
3) *American Journal of Kidney Disease,* [referenced through Elsevier Bibliographic Database, EMBASE/Excerpta Medica, MEDLINE] Associate Editor, 2006 to 2019, Guest Editor, 2011, 2012
4) *Arquivos Brasileiros de Cardiologia*, International Editorial Board, 2006 to present
5) *Biocritique*, Editorial Board, 2001 to 2013, www.biocritique.com
6) *Blood Purification, Editorial Board 2018 to present*
7) *Cardiovascular Clinician,* Editorial Board, 2011 to 2013, internet site, CARDIOVASCULARClinician.com™
8) *Cardiovascular Diagnosis and Therapy (CDT),* Editorial Board *(*Print ISSN: 2223-3652; Online ISSN: 2223-3660, 2012 to present
9) *Cardiovascular Innovations and Applications (CVIA),* Editorial Board 2015 to present
10) *Cardiorenal Medicine,* Associate Editor, 2016-2017, Editor-in-Chief 2018 to present
11) *Circulation,* Editorial Board, 2016 to present
12) *Circulation Heart Failure,* Editorial Board, 2008 to present, Associate Editor, 2008 to 2016, Guest Editor 2010, 2011, 2012
13) *Clinical Exercise Physiology,* Clinical Consultant to the Editorial Board, 1998-2002.
14) *Cochrane Renal Group Module*, 2008, Editorial Contributor, Centre for Kidney Research, The Children's Hospital at Westmead, Westmead NSW, Australia
15) *Expert Review of Cardiovascular Therapy*, Editorial Advisory Panel, 2002 to present, www.future-drugs.com
16) *Journal of the American College of Cardiology,* Editorial Consultant, 2003-present. "Elite Reviewer" Recognition, 2004, 2005, 2006, 2007, 2008, 2011, 2014, 2016 (DeMaria AN. The elite reviewer. J Am Coll Cardiol 2003;41(1):157-8.)
17) *Journal of Geriatric Cardiology,* Editorial Board Member, 2003-present. The Institute of Geriatric Cardiology, Chinese PLA Hospital, Beijing. [Joint China-U.S.A. publication]
18) *Journal of Biorepository Science for Applied Medicine,* Honorary Editorial Board, 2012 to 2018

19) *Journal of Clinical & Experimental Cardiology*, OMICS Publishing Group, Open Access, CrossRef, PubMed, DOAJ, Index Copernicus, Scientific Commons, EBSCO, 2010 to 2017
20) *Journal of Diabetes & Metabolism,* OMICS Publishing Group, Open Access, 2010 to 2017
21) *Journal of Interventional Cardiology,* "News and Views", Section Editor, 2000-2003. Editorial Board Member, 2003 to present
22) *Journal of Nephrology and Therapeutics,* Editorial Board, OMICS Publishing Group, Editorial Board, 2010 to 2017
23) *Reviews in Cardiovascular Medicine, MedReviews, LLC,* www.medreviews.com "Cardiorenal Function," Section Editor, 2001-2002, Associate Editor, 2003-2009, Co-Editor, 2009 to present
24) *The American College of Cardiology Foundation ACCEL Audio Journal,* Editorial Board 2008 to present
25) *The Open Atherosclerosis & Thrombosis Journal,* [referenced through Bentham Open, PubMed, Google and Google Scholar] Editorial Board, 2008 to 2012
26) *The Open Heart Failure Journal,* [referenced through Bentham Open, PubMed, Google and Google Scholar] Editorial Board, 2008 to 2010
27) *Therapy,* [referenced through Elsevier Bibliographic Database, EMBASE/Excerpta Medica, MEDLINE], Editorial Board, 2008 to 2010

Manuscript Reviewer

1) *Advances in Chronic Kidney Disease,* 2004 to present (18)
2) *Advances in Medical Sciences*, 2012 to present (2)
3) *Advances in Therapy,* 2008 to present (1).
4) *American Family Physician,* 2004 to present (2)
5) *American Journal of Cardiovascular Drugs*, 2002 to present. (2)
6) *American Heart Journal (AHJ),* 1998 to present (22)
7) *American Journal of Cardiology (AJC),* 1999 to present (60)
8) *American Journal of Human Biology,* 2014 to present (1)
9) *American Journal of Hypertension,* 2011 to present (1)
10) *American Journal of Kidney Diseases (AJKD),* 2002 to present (30)
11) *American Journal of Medicine (AJM)*, 1997 to present (7)
12) *American Journal of the Medical Sciences (AJMS),* 2006 to present (3)
13) *American Journal of Nephrology,* 2004 to present (24)
14) *American Journal of Physiology: Renal Physiology,* 2006 to present (2)
15) *American Journal of Transplantation,* 2004 to present (1)
16) *Annals of Epidemiology,* 2004 to present (1)
17) *Annals of Internal Medicine,* 2008 to present (3)
18) *Annals of Noninvasive Electrocardiology,* 2009 to present (1)
19) *Antimicrobial Agents and Chemotherapy,* 2020 to present (1)
20) *Archives of Internal Medicine,* 2004 to present (2)
21) *Archives of Pathology and Laboratory Medicine,* 2007 to present (1)
22) *Arteriosclerosis, Thrombosis, and Vascular Biology,* 2010 to present (2)
23) *Autonomic Neuroscience: Basic and Clinical,* 2007 to present (1)

24) *BUMC Proceedings,* 2012 to present (3)
25) *Biochemia Medica,* 2012 to present (1)
26) *Biomed Central (BMC) Medical Imaging,* 2010 to present (1)
27) *Blood Purification,* 2010 to present (2)
28) *BMC Medicine,* 2007 to present (1)
29) *BMC Nephrology,* 2011 to present (1)
30) *BMJ Clinical Evidence,* 2008 to present (1)
31) *British Medical Journal (BMJ)*, 2009 to present (1)
32) *Canadian Medical Association Journal (CMAJ),* 2006 to present (3)
33) *Cardiac Failure Review,* 2015 to present (1)
34) *Cardiology,* 2007 to present (1)
35) *Cardiorenal Medicine;* 2013 to present (10)
36) *Cardiovascular Innovations and Applications,* 2016 to present (1)
37) *Cardiovascular Therapeutics,* 2010 to present (1)
38) *Catheterization and Cardiovascular Interventions*, 2000 to present (6)
39) *Chest,* 2000 to present (6)
40) *Circulation*, 1998 to present (100)
41) *Circulation Cardiovascular Interventions,* 2012 to present (1)
42) *Circulation Cardiovascular Quality and Outcomes,* 2010 to present (1)
43) *Circulation Heart Failure,* 2009 to present (4)
44) *Circulation Imaging,* 2012 to present (1)
45) *Cleveland Clinic Journal of Medicine,* 2008 to present (1)
46) *Clinica Chimica Acta,* 2013 (1)
47) *Clinical Cardiology,* 2001 (3)
48) *Clinical Chemistry and Laboratory Medicine,* 2010 to present (2)
49) *Clinical Exercise Physiology,* 2000-2002 (4)
50) *Clinical Journal of the American Society of Nephrology* 2008 to present (3)
51) *Clinical Kidney Journal*, 2012 to present (1)
52) *Clinical Medicine and Research,* 2008 to present (1)
53) *Clinical Nephrology,* 2008 to present (2)
54) *Clinical Physiology and Functional Imaging,* 2010 to present (1)
55) *Clinical Researcher*, 2002 to present (1)
56) *Clinics,* 2010 to present (1)
57) *Cochrane Collaboration,*2009 to present (2)
58) *Congestive Heart Failure,* 2005 to present (4)
59) *Coronary Artery Disease,* 2005 to present (1)
60) *Critical Care Medicine,* 2008 to present (2)
61) *Current Medical Research and Opinion,* 2005 to present (1)
62) *Diabetes Care,* 2011 to present (2)
63) *Diabetes and Vascular Disease Research*, 2011 to present (1)
64) *Diabetes, Obesity, and Metabolism,* 2019 to present (1)
65) *Diabetic Medicine,* 2008 to present (1)
66) *Drug Benefit Trends,* 1999 (1)
67) *Drugs,* 2000 (2)

68) *European Heart Journal*, 1995 (12)
69) *European Journal of Cardiovascular Prevention and Rehabilitation*, 2006 (1)
70) *European Journal of Heart Failure,* 2012 (4)
71) *Expert Opinion on Pharmacotherapy,* 2003 to present (3)
72) *Expert Opinion Therapeutic Patents,* 2004 to present (1)
73) *Expert Review of Cardiovascular Therapy,* 2008 to present (2)
74) *Global Heart*, 2012 (1)
75) *Heart,* 2004 (2)
76) *Heart and Vessels,* 2007 (2)
77) *Hemodialysis International* 2013 (2)
78) *Internal Medicine Journal (Australasia),* 2009 to present (1)

79) International Journal of Infectious Diseases 2020 to present (2)
80) *International Journal of Nephrology,* 2010 to present (2)
81) *Journal of Biomarkers,* 2013 (1)
82) *Journal of Geriatric Cardiology,* 2017 (1)
83) *Journal of Internal Medicine,* 2009 to present (1)
84) *Journal of Interventional Cardiology (JIC)*, 1996 to present (9)
85) *Journal of the American College of Cardiology (JACC)*, 1998 to present (228)
86) *Journal of the American College of Cardiology: Heart Failure (JACC Heart Fail)*, 2014 to present (12)
87) *Journal of the American College of Cardiology: Imaging (JACC Imag)*, 2014 to present (6)
88) *Journal of the American College of Cardiology: Interventions (JACC Interv)*, 2010 to present (10)
89) *Journal of the American Medical Association (JAMA),* 2002 to present (60)
90) *Journal of the American Medical Association Cardiology (JAMA Cardiology),* 2016 to present (20)
91) *Journal of the American Society of Echocardiography (JASE)*, 2009 to present (1)
92) *Journal of the American Society of Nephrology (JASN)* 2005 to present (14)
93) *Journal of Cardiac Failure,* 2003 to present (10)
94) *Journal of Clinical Outcomes Management*, 2011 to present (1)
95) *Journal of Critical Care,* 2011, to present (1)
96) *Journal of General Internal Medicine,* 2008 to present (1)
97) *Journal of Human Hypertension,* 2010 to present (1)
98) *Journal of Inherited Metabolic Disease,* 2014 to present (2)
99) *Journal of Lipid Research,* 2010 to present (1)
100) *Journal of Managed Care,* 2004 to present (1)
101) *Journal of Physiology and Pathophysiology*, 2009 to present (1)
102) *Kidney and High Blood Pressure Research,* 2008 to present (1)
103) *Kidney International,* 2004 to present (8)
104) *Medical Science Monitor,* 2008 to present (1)
105) *Medicine & Science in Sports and Exercise,* 2005 to present (3)
106) *Nature Clinical Practice Cardiovascular Medicine*, 2004 to present (4)
107) *Nature Clinical Practice Nephrology*, 2008 to present (1)

108) *Nature Reviews Nephrology,* 2009 to present (3)
109) *Nephron,* 2005 to present (1)
110) *Nephrology,* 2009 to present (1)
111) *Nephrology, Dialysis, and Transplantation,* 2005 to present (7)
112) *New England Journal of Medicine,* 2006 to present (8)
113) *Pharmacological Research (Italy),* 1999 (1)
114) *Pharmaceutical Sciences,* 2011 (1)
115) *PLoS Medicine,* 2005 (1)
116) *PLOS ONE,* 2013 (1)
117) *Prehospital Emergency Care*, 2015 (1)
118) *Preventive Medicine,* 2008 (1)
119) *Rejuvenation Research,* 2007 (1)
120) *Renal Failure*, 2011 (2)
121) *The Lancet,* 1999 to present (11)
122) *The Lancet Diabetes,* 2013 to present (5)
123) *The Lancet Global Health,* 2015 to present (2)

Major Meeting Abstract Grader

1) ACC Scientific Sessions 2001 to present (10)
2) ACC I2 Summit, 2006 to present (2)
3) American Diabetes Association, 2008 to present (13)
4) AHA Scientific Sessions, 1997 to present (8)
5) American Medical Informatics Association, Annual Symposium, 1998-2001 (3)
6) International Academy of Cardiology World Congress on Heart Disease, Academy of Cardiology Annual Scientific Sessions—Mechanisms and Management, 2002-present (3)
7) Transcatheter Therapeutics (TCT), 2004 (1)

Grant Reviewer

1. National Medical Research Council, Singapore, 2003-2004
2. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Special Emphasis Panel/Initial Review Group 2006/01 ZDK1 GRB-9, 2005
3. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Special Emphasis Review Group, 1 R01 DK070033-01A2, 2006
4. National Institutes of Health, National Heart Lung and Blood Institute, Study Section, ZHL1 CSR-H (M1), March 6-7, 2006, Heart Failure Network
5. Diabetes UK, The British Diabetic Association, Macleod House, 10 Parkway, London NW1 7AA. December 24, 2008
6. National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases, Special Review Panel, Chronic Renal Insufficiency Cohort Study (CRIC) and A Prospective Cohort Study of Kidney Disease in Children (CKiD) Study, February 23-25, 2012, March 6, 2013

7. National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases, Special Review Panel, ZDK1 GRB-7 (O3)S in response to PAR-DK-09-247: Ancillary Studies to Major Ongoing Clinical Research Studies to Advance Areas of Scientific Interest within the Mission of the NIDDK (R01), July 11, 2012
8. Alberta Innovates Health Solutions Collaborative Research & Innovation Opportunities (CRIO) Grant Review, September, 2012
9. Health Research Board of Ireland, Health Research Awards, 2013
10. National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases 2017/01 ZRG1 DKUS-R (55) Study Section 2016

Guidelines Reviewer

1. Kidney Disease Improving Global Outcome (KDIGO) Guidelines Review
    a. Prevention, Diagnosis, Evaluation and Treatment of Hepatitis C in Chronic Kidney Disease, Published April, 2008
    b. Diagnosis, Evaluation, Prevention and Treatment of Chronic Kidney Disease related Mineral and Bone Disorders (CKD-MBD), Published August, 2009
    c. Acute Kidney Injury (AKI), published March, 2012

CLINICAL TRIAL AND STUDY RESPONSIBILITIES

Overall Study Responsibilities: Steering and Executive Committees

1) Study Principal Investigator, Medicine vs Angiography for Thrombolytic Exclusion Patients (M.A.T.E.), 1994-1997, (multicenter, U.S., randomized controlled trial [RCT]). Status: closed.

2) Study Principal Investigator, The Resource Utilization Among Congestive Heart Failure Study (R.E.A.C.H.), 1998-2000, (single-center, prospective cohort study). Status: closed.

3) Study Principal Investigator, The Asthma, Beta-Agonists, and Congestive Heart Failure Study, (A.B.C.H.F.), 1998-1999, (single-center, case-control study). Status: closed.

4) Study Co-Principal Investigator, The Prevention of Radiocontrast Induced Nephropathy Clinical Evaluation (P.R.I.N.C.E.) Study, 1995-1998, (single-center, RCT). Status: closed.

5) Study Co-Principal Investigator, BNP Multinational Study, Principal Investigator, Alan Maisel, MD, Biosite Diagnostics, Inc., 2000-2006, (multicenter, international, prospective cohort study). Status: closed.

6) Study Co-Investigator, Prophylactic Oral Amiodarone Compared to Placebo for Prevention of Atrial Fibrillation Following Coronary Artery Bypass Graft Surgery (P.A.P.A.C.A.B.G.), 1996-1998, (single-center, RCT). Status: closed.

7) Study Co-Investigator, Rapid Early Bedside Markers of Myocardial Injury, 1998-1999, HFHS and Biosite Diagnostics, Inc. (prospective cohort study). Status: closed.

8) Member, Steering Committee, Clinical Study Protocol No. 2000-025: A Phase IIIb, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Safety, Efficacy, and Tolerability of Fenoldopam Mesylate in Subjects Undergoing Interventional Cardiology Procedures (CONTRAST), William W. O'Neill, MD and Gregg Stone, MD, Co-Principal Investigators, Abbott Laboratories, Inc., 2000-2003 (multicenter, US, RCT). Status: closed.

9) Chair, National Steering Committee, Kidney Early Evaluation Program (KEEP) NKF, Member 2000-2005, Co-Chair 2005-2010, Chair 2010-present (multicenter, U.S., prospective cohort study). Annual budget ~$1,325,198 (2009), ~$1,233,832 (2010), ~$1,614,953.00 (2011), ~$989,500 (2012), ~$1,217,000 (2013). Status: inactive.

10) Member, Steering Committee, Protocol No. 704.351 Evaluation of Synergy between Natrecor and Furosemide on Renal and Neurohormone Responses in Chronic Heart Failure: A Phase IV Study, Scios Inc., 2003-2005 (multicenter, U.S., randomized cross-over trial). Status: closed.

11) Member, Steering Committee, Protocol No. CCIB002FUS12. A Multicenter, Double-blind, Randomized, Parallel Group Study to Evaluate the Effects of Lotrel and Lotensin HCT on Microalbuminuria in Mild to Moderate Hypertensive Subjects with Type 2 Diabetes Mellitus, Novartis Pharmaceuticals, Inc., 2003-2006. Status: closed.

12) Rotating Executive Committee Principal Investigator Member, NIH HF-ACTION Trial (Exercise Training Program to Improve Clinical Outcomes in Individuals With Congestive Heart Failure), HL63747 01A2, 2006-2009. Principal Investigator, David Whellan, MD, status: closed.

13) Overall Study Principal Investigator, Neutrophil Gelatinase-Associated Lipocalin: A Novel Blood Marker for Risk of Developing Contrast Induced Nephropathy (ENCINO), multicenter, prospective, blinded cohort study, 2006-2009, status: closed.

14) Member, Steering Committee, VA NEPHRON-D: Diabetes iN Nephropathy Study, 2008 to 2013, trial stopped early for safety cardiovascular and acute kidney safety concerns in angiotensin converting enzyme inhibitor plus losartan arm, status: closed.

15) Member, External Expert Panel, National Institutes of Health, National Institute of Digestive and Diabetes and Kidney Diseases, Chronic Renal Insufficiency Cohort Study, status open, 2010 to present.

16) Member, Optimal Medical Management Subcommittee, National Institutes of Health, National Heart Lung and Blood Institute, International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA), status: open, 2011 to present.

17) Member, Steering Committee, National Institutes of Health, National Heart Lung and Blood Institute, International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) in patients with Chronic Kidney Disease (ISCHEMIA-CKD), status: open, 2012 to present.

18) Member, Steering Committee, Thrasos Innovation, Inc, A Phase II Multi-Center, Parallel-Group, Randomized, Double Blind, Proof-of-Concept, Adaptive Study Investigating the Safety and Efficacy of THR-184 Administered via Intravenous Infusion in Patients at Increased Risk of Developing Cardiac Surgery Associated-Acute Kidney Injury (CSA-AKI), status: closed, 2012 to 2015.

19) Overall Principal Investigator, AbbVie, Inc, Clinical Study Protocol M13-796, A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Trial of Multiple Dosing Regimens of ABT-719 for the Prevention of Acute Kidney Injury in Subjects Undergoing High Risk Cardiac Surgery, status: closed, 2013 to 2014.

20) Overall Principal Investigator, Bioporto, Inc, The NGAL Test™ As An Aid in the risk assessment for AKI stage II and III in an Intensive Care Population, status: open 2017 to present.

21) Member, Global Expert Panel, Novo Nordisk, Inc, A Research Study to See How Semaglutide Works Compared to Placebo in People With Type 2 Diabetes and Chronic Kidney Disease (FLOW), status: open.

Overall Study Responsibilities: Endpoint Committees

1) Member, Critical Endpoints Committee, Treat Angina with Aggrastat and Determine Cost of Therapy with an Invasive or Conservative Strategy, TACTICS-TIMI 18 (Protocol 019-00), 1998-2000, (multicenter, international, RCT). Status: closed

2) Member, Study Endpoints Committee, A Phase II, Escalation Trial of Vasoflux™ in Patients Undergoing Thrombolysis with Streptokinase for Acute Myocardial Infarction, Protocol CLN-P-V18-07001, Parexel International Corporation,1998, (multicenter, international, RCT). Status: closed

3) Member, Safety Endpoint Evaluation Committee, A Phase III, Single-Blind Controlled Study to Evaluate the Clinical Effects of a Hemoglobin-based Oxygen Carrier (HBOC-210) Given as a Transfusion Alternative in Patients Undergoing Orthopedic Surgery. (Protocol HEM-0115), Biopure Corporation with Quintiles, Inc., Clinical Event and Adjudication Services, 2000-2001. (multicenter, international, RCT). Status: closed

4) Member, Critical Endpoints Committee, Cerivastatin Heart Outcomes in Renal Disease: Understanding Survival (C.H.O.R.U.S.), Barry Brenner, MD and William F. Keane, MD, Co-Principal Investigators, Bayer Inc., 2000-2003 (multicenter, international, RCT). Status: study terminated early due to drug withdrawal from market

5) Member, Clinical Events Classification Committee, Correction of Hemoglobin and Outcomes in Renal Insufficiency (CHOIR), Ajay Singh, MD, Donal Reddan, MBBS, Principal Investigators, Ortho Biotech Inc., 2001-2004 (multicenter, international, RCT). Status: closed

6) Member, Critical Endpoint Committee, A Randomised, Double-blind, Parallel Group, Phase 3, Efficacy and Safety Study of AZD6140 (Ticagrelor) Compared with Clopidogrel for Prevention of Vascular Events in Patients with Non-ST or ST Elevation Acute Coronary Syndromes (ACS) [PLATO – A Study of PLATelet inhibition and Patient Outcomes.], AstraZeneca, Inc., Duke Clinical Research Institute, 2008, status: closed

7) Chair, Clinical Endpoints Committee, Alere San Diego, Inc, Alere Prospective Blinded Study of a Novel Troponin Assay (PEARL), status: closed 2015

8) Chair, Adjudication Committee, Myeloperoxidase In the Diagnosis of Acute coronary Syndromes (MIDAS) study, Alere, Inc., status: closed 2012

9) Independent Endpoint Adjudicator, BioPorto Diagnostics, The NGAL test as an aid for the Diagnosis of AKI in an Intensive Care Population, Code of the Study: KLIN 12-005, status closed, 2015

10) Independent Endpoint Adjudicator, Ischemix, Inc., Safety and Efficacy of CMX-2043 for Protection of the Heart and Kidneys in Subjects Undergoing Coronary Angiography (CARIN), status: closed 2016

11) Chair, Data Adjudication Committee, Estimating versus Measuring Plasma Volume and Kidney Function in Acute Decompensated Congestive Heart Failure, Eudra-CT Number 2018-002638-18, Sponsor: Charite-Unversitatsmedizin Berlin, FAST Biomedical, Inc, 2018-present

Overall Study Responsibilities: Data Safety Monitoring Committees

1) Member, External Advisory Committee/Data Safety Monitoring Board, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Polycystic Kidney Disease (PKD) Clinical Trials Network HALT-PKD Trial, Robert Schrier, MD, Principal

Investigator, Committee Chair: William Henrich, MD, 2004-2008, Data Safety Monitoring Board, status: closed 2014

2) Chairman, Data Safety Monitoring Committee, Clinical Trials Program CS0011-A-U301, Daiichi Sankyo Pharma Development (DSPD) CS-011, Seven Core Trials of Rivoglitazone in Type 2 Diabetes: 1) A 26-week placebo-controlled trial of 1.0 and 1.5 mg rivoglitazone vs. 45 mg pioglitazone, as monotherapy in type 2 diabetics (CS0011-A-U301); 2) A 26-week placebo-controlled trial of 0.5, 1.0 and 1.5 mg rivoglitazone vs. 15, 30 and 45 mg pioglitazone, as monotherapy in type 2 diabetics (CS0011-A-U302); 3) A 26-week placebo-controlled trial of 1.0 and 1.5 mg rivoglitazone vs. 45 mg pioglitazone, in type 2 diabetics on metformin therapy, followed by a 26-week pioglitazone-controlled continuation period (CS0011-A-U303); 4) A 26-week placebo-controlled trial of 0.5 and 1.0 rivoglitazone vs. 30 mg pioglitazone, in type 2 diabetics on sulfonylureas therapy, followed by a 26-week pioglitazone-controlled continuation period (CS0011-A-U304); 5) A 26-week placebo-controlled trial of 0.5 and 1.0 mg rivoglitazone vs. 15 mg pioglitazone in type 2 diabetics on insulin therapy (CS0011-A-U305); 6) A long-term (12-24 months) randomized, general efficacy and safety study of rivoglitazone vs. pioglitazone, as monotherapy or add-on therapy, in type 2 diabetics (CS0011-A-U306); 7) A 26-week placebo-controlled trial of rivoglitazone and metformin, in type 2 diabetics (CS0011-A-U307), USFDA Special Protocol Assessment Agreement granted, status: closed, 2009 trials program terminated

3) Member, Data Safety Monitoring Committee, A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Cardiovascular Outcomes Following Treatment with Alogliptin in Addition to Standard of Care in Subjects with Type 2 Diabetes and Acute Coronary Syndrome SYR322_402, EXAMINE Trial Takeda Global Research and Development Center, Inc. (US) Takeda Global Research and Development Centre, Ltd. (Europe), status: 2009 trial stopped early for non-inferiority but futility on superiority outcome

4) Chair, Data Safety Monitoring Committee, Protocol D9120C00019, A randomised, double-blind, placebo controlled, multi-centre phase IIb dose finding study to assess the effect on GERD symptoms, safety and tolerability during four weeks treatment with AZD3355 in doses 60 mg, 120 mg, 180 mg and 240 mg bid as add-on treatment to a PPI in patients with GERD that are partial responders to PPI treatment, AstraZeneca, status: closed 2009, trials program terminated for safety

5) Member, Data Safety Monitoring Committee, Protocols: AMAG-FER-IDA-301, A Phase III, Randomized, Double-Blind, Placebo-Controlled Trial of Ferumoxytol for the Treatment of Iron Deficiency Anemia, Protocol: AMAG-FER-IDA-302, A Phase III, Randomized, Open-Label, Active Controlled Trial Comparing Ferumoxytol with Iron Sucrose for the Treatment of Iron Deficiency Anemia, Protocol: AMAG-FER-IDA-303, A Phase III, Open-Label Extension, Trial of the Safety and Efficacy of Ferumoxytol for the Episodic Treatment of Iron Deficiency Anemia, AMAG Pharmaceuticals, Inc., status: closed 2010, trial completed in 2013 without safety concerns

6) Chair, Independent Data Monitoring Committee, Protocol 402-C-0903 Bardoxolone Methyl Evaluation in Patients with Chronic Kidney Disease and Type 2 Diabetes: the Occurrence of Renal Events (BEACON), Reata Pharmaceuticals, Inc., status: trial stopped in 2012 early for cardiovascular and mortality safety concerns

7) Member, Independent Safety Council, Affymax Inc and Takeda Pharmaceutical Co., Omontys (peginesatide), status: closed, post-marketing surveillance led to voluntary drug withdrawal from market in 2013 for serious and fatal allergic reactions

8) Chair, Independent Data Monitoring Committee, AbbVie, Inc, Clinical Study Protocol M11-352 A Randomized, Multicountry, Multicenter, Double Blind, Parallel, Placebo-Controlled Study of the Effects of Atrasentan on Renal Outcomes in Subjects with Type 2 Diabetes and Nephropathy SONAR: Study Of Diabetic Nephropathy with Atrasentan, status closed 2018

9) Chair, Independent Data Monitoring Committee, AbbVie, Inc., Clinical Study Protocol M13-958 A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Trial of Multiple Dosing Regimens of ABT-719 for the Prevention of Acute Kidney Injury in Subjects Undergoing High Risk Major Surgery, status: closed 2015

10) Member, Data Monitoring Committee, Akebia Therapeutics, Inc., AKB-6548-CI-0007, Phase 2b Randomized, Double-Blind, Placebo-Controlled Study to Assess the Pharmacodynamic Response, Safety, and Tolerability to 20 Weeks of Oral Dosing of AKB-6548 in Subjects with Anemia Secondary to Chronic Kidney Disease (CKD), GFR Categories G3a-G5 (Stages 3, 4, and 5) (Pre-Dialysis), status: closed 2015

11) Member, Study Monitoring Team, Akebia Therapeutics, Inc., AKB-6548-CI-0011, Phase 2a Open-Label Study to Assess the Efficacy, Safety, and Tolerability of AKB-6548 in Subjects with Anemia Secondary to End Stage Renal Disease (ESRD), Undergoing Chronic Hemodialysis, status: closed 2016

12) Member, Data Monitoring Committee, Merck, Inc., Pfizer, Inc, Clinical Trials Program, Ertugliflozin (MK-8835/PF-04971729) Phase 2 and Phase 3 Development Program, status closed, 2012 to 2020

13) Member, Steering Committee, Medtronic, Inc., Monitoring in Dialysis, status: closed 2016

14) Member, Data Safety and Monitoring Board, St. Jude Medical, EnligHTN IV Multi-center, randomized, single-blind, sham controlled clinical investigation of renal denervation for uncontrolled hypertension, status: 2013 trial terminated before recruitment started

15) Chair, Data Safety Monitoring Board, Neumedicines, Inc., A Phase 2, Single-Dose, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability,

Pharmacokinetics, and Pharmacodynamics of HemaMax™ (rHuIL-12) in Healthy Subjects, status: closed 2016

16) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., A Phase 2 Study of the Safety, Efficacy, and Pharmacodynamics of RTA 408 in the Treatment of Friedreich's Ataxia, 2014 to 2019, status: closed

17) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., A Phase 2 Study of the Safety, Efficacy, and Pharmacodynamics of RTA 408 in the Treatment of Mitochondrial Myopathy, 2015 to 2019, status: closed

18) Member, Patient Safety Review Committee, Reata Pharmaceuticals, Inc, A dose-ranging study of the efficacy and safety of Bardoxolone Methyl in patients with pulmonary arterial hypertension (402-C-1302), 2014 to 2018, status: closed

19) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., A Study of the Efficacy and Safety of Bardoxolone Methyl in Patients with Connective Tissue Disease-Associated Pulmonary Arterial Hypertension (CATALYST), 2016 to present, status: closed

20) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., A Phase 2/3 of Efficacy and Safety of Bardoxolone Methyl in Patients with Alport Syndrome (CARDINAL), 2017 to present, status: closed

21) Chair, Data Safety Monitoring Board, Sanfit, Inc., A double-blind, randomised, placebo-controlled study to assess the effect of SNF472 on progression of cardiovascular calcification on top of standard of care in end-stage-renal-disease (ESRD) patients on haemodialysis (HD) SNFCT2015-05, 2017 to 2019, status: closed

22) Chair, Data Monitoring Committee, Renew Research, KAI Research, A Randomized Pivotal Study of RenewTM NCP-5 for the Treatment of Mild Cognitive Impairment due to Alzheimer's Disease or Mild Dementia of the Alzheimer's Type, 2018 to present, status: closed

23) Chair, Data Safety Monitoring Committee, Sanofi, Inc, Multicenter, randomized, double-blind, placebo-controlled two stage study to characterize the efficacy, safety, tolerability and pharmacokinetics of GZ/SAR402671 in patients at risk of rapidly progressive Autosomal Dominant Polycystic Kidney Disease (ADPKD) STUDY NUMBER: EFC15392 STUDY NAME: SAVE-PKD COMPOUND: GZ/SAR402671, 2018 to present, status: open

24) Chair, Data Safety Monitoring Board, National Institutes of Health, National Heart, Lung and Blood Institute R34 NHLBI Clinical Trial Pilot Studies (R34) Reducing Arrhythmia in Dialysis by Adjusting the Rx Electrolytes/Ultrafiltration (RADAR), David Charytan, MD, PI, 2019 to present, status: open

25) Chair, Data Safety Monitoring Board, GZ402671 EFC15392 Multicenter, randomized, double-blind, placebo-controlled two stage study to characterize the efficacy, safety, tolerability and pharmacokinetics of GZ/SAR402671 in patients at risk of rapidly progressive Autosomal Dominant Polycystic Kidney Disease (ADPKD), Sanofi, status: open

26) Chair, Data Safety Monitoring Board, MEDI3506, Trials Portfolio, D9182C00001 A Phase 2 Randomized, Double-blinded, Placebo-controlled Study to Evaluate the Efficacy and Safety of MEDI3506 in Adult Subjects with Moderate-to-severe Atopic Dermatitis; D9181C00001 A Phase II, Randomised, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of MEDI3506 in Adult Participants with Uncontrolled Moderate-to-severe Asthma; D9180C00002 A Phase II, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy, Safety and Tolerability of MEDI3506 in Participants with Moderate to Severe Chronic Obstructive Pulmonary Disease and Chronic Bronchitis (FRONTIER 4); D9183C00001 A Phase 2b Randomized, Double-blind, Placebo-controlled, Study to Evaluate the Efficacy and Safety of MEDI3506 in Subjects with Diabetic Kidney Disease, Axio Inc, A Cytel Company, status: open

GRANT AWARDS

Original Research Grants

G1) London JF (PI), Bis KG, Juni JE, Wilke N, DiCarli MF, Shetty AN, **McCullough PA**, Timmis GC. Magnetic Resonance vs. Positron Emission Tomography for the Detection of Myocardial Viability. Bracco Diagnostics Inc./SCA&I Grant, $25,000 (WBH RC-453), 1997-98. Additional WBH Research Institute Mini-grant, $5,000 (WBH Grant #RC-748). Level of involvement: author of the variable definitions, endpoints, and data analysis sections, 0% FTE. Status: closed 1998

G2) **McCullough PA** (PI), Shah S, Noor H, Marks KR, McCabe KB, Zong L, McCord J, Khoury N, Ulcickas-Yood M, Ward RE. Diagnostic Accuracy of an Emergency Department Clinical Decision Unit in the Evaluation of Chest Pain. HFHS Small Projects Fund $10,000 (HFHS Grant #A30785), 0% FTE. Status: closed 1997

G3) Keteyian SJ (Co-PI), **McCullough PA** (Co-PI), Brawner CA, Rosman HS, Stein P, Weaver WD. A Prospective Study of Case Identification and Triage of Patients Eligible for Cardiac Rehabilitation. Merck & Co., U.S. Human Health, $30,000 (HFHS Grant #E18037), 3% FTE. Status: closed 1998

G4) **McCullough PA.** Novel Methods for Identifying High-Risk Patients for Subsequent Cardiovascular Events. Merck & Co., U.S. Human Health, $20,000 (HFHS Grant #M1060), 0% FTE. Status: closed 1998

G5) **McCullough PA.** Cardiovascular Informatics Development Award. Pfizer, Inc., $10,000 (HFHS Grant #E60022), 0% FTE. Status: closed 1998

G6) **McCullough PA,** Yee J, Soman S, Sallach J, Borzak S, Foreback C, Monaghan K, Tisdale JE, Bailey E, Bola P, Chase G, Marks KR, Weaver WD. A Prospective Dose-Ranging Trial of Folic Acid to Reduce Total Homocyst(e)ine Levels in Patients with End-Stage Renal Disease Undergoing Hemodialysis. HFHS Project Development Fund $10,000 (HFHS Grant #A20003), 0% FTE. Status: closed 1999

G7) **McCullough PA.** NuStep Recumbent Cross Trainer Product Development Pilot Study, NuStep, Inc., (single center, prospective pilot study), $12,500.00, (WBH Grant #RC- 08-94847). Status: closed 2005

G8) **McCullough PA,** Secondary Analyses from the PRINCE Trial, (single center data analysis), $20,000, PLC Medical, Inc., (WBH #RC 08-94851) Status: closed 2005

G9) **McCullough PA**, Sullivan RA. A Systematic Review of Vascular Calcification in Patients with Chronic Kidney Disease and End-Stage Renal Disease, 2002-2003, Braintree Labs, Inc., $40,000, 25% FTE (WBH Grant #RC 08-94833) Status: closed 2003

G10) Pasas SA, Davies MI, **McCullough PA.** Determination of Protein-bound Homocysteine in Human Plasma using Capillary Electrophoresis with Electrochemical Detection in Patients with Chronic Kidney Disease, 2003-2004, AHA Predoctoral Fellowship Program (Pasas), $38,000, 15% FTE (UMKC Grant #). Status: closed 2003

G11) Collins AC, Gladstone E, Robitscher JW, **McCullough PA**, Klag M, Narva A, Gilberston D for the NKF. Demonstration project: state-based screening for chronic kidney disease. Response to CDC-RFA-DP06-004, demonstration project for identifying individuals at high-risk for CKD in the US. Centers for Disease Control, $1,199,609, 12% FTE Status: closed 2007

G12) **McCullough PA**, Principal Investigator. Neutrophil Gelatinase-Associated Lipocalin (NGAL): A Novel Blood Marker for Risk of Developing Contrast-Induced Nephropathy (ENCINO). Biosite/Inovise, Inc., $229,000.00 (WBH #RC-94862), 0% FTE Status: closed 2009

G13) Agrawal V, Barnes M, **McCullough PA.** Evaluation of CKD awareness in medical residents. WBH intramural mini-grant R/C# 98662, $10,000.00, 0% FTE Status: closed 2008

G14) **McCullough PA,** overall Principal Investigator transferred to Zalesin K. FDA Investigational New Drug Exemption (INDE) #060672. A Prospective, Randomized, Placebo-Controlled, Parallel-Group, Pilot Trial of Paricalcitol in the Treatment of Hyperparathyroidism in Patients after Roux-en-Y Gastric Bypass Surgery with Chronic Kidney Disease, Abbott Laboratories, Inc., $496,600.00 (WBH #RC-90290), 0% FTE Status: closed 2009

G15) **McCullough PA**, overall Principal Investigator transferred to Miller WM, FDA INDE #107750. Investigator Initiated Study. A Prospective, Double-Blind, Randomized, Parallel Group, Placebo-Controlled Trial of Aliskiren versus Placebo in Non-Diabetic, Normotensive Obese Patients with Microalbuminuria, Novartis, Inc., $339,400.00 (WBH #RC-90345), Status: closed 2010

G16) **McCullough PA,** overall Principal Investigator. Investigator Initiated Study, FDA Investigational New Drug (IND) #74707. A Phase 2, randomized, double-blind, placebo-controlled trial, to assess the efficacy and safety of deferiprone in the reduction of markers of contrast-induced acute oxidative kidney injury. Cormedix, Inc, $857,745 (includes $101,442 for Beaumont Research Coordinating Center). Study centers included Providence Hospital and Medical Center Southfield, St. John Hospital and Medical Center, Detroit, Northern Michigan Hospitals, Petoskey, MI, St. Vincent's Hospital, Indianapolis, IN, Fairfield Cardiac Cath Labs, LLC, Fairfield, OH, Oklahoma Heart Hospital, Oklahoma City, OK, Ohio Health Research Institute, Columbus, OH, Mercy St. Vincent Hospital, Toledo, OH, Status: closed 2011

G17) **McCullough PA,** overall study Principal Investigator, A Prospective Randomized Parallel-Group Controlled Trial of Multiple Blood Biomarkers in the Personalized Management of Chronic Heart Failure, Baylor IRB 014-252, Baylor Foundation, 2014, $78,639.20, status: closed 2016.

G18) **McCullough PA**, overall study Principal Investigator, Baylor Hypertrophic Cardiomyopathy Program Development Project: Time-resolved, 3D phase contrast magnetic resonance imaging (MRI) (4D Flow) and Advanced Strain Rate Echocardiography in Patients with Hypertrophic Cardiomyopathy, Baylor IRB 014-175, Baylor Foundation, 2014, $100,000.00, status: open

G19) **McCullough PA,** overall study Principal Investigator, Preventive Cardiology Registry: Role of Proprotein Convertase Subtilisin/kexin type 9 (PCSK9) and Other Catabolic Determinants in Hypercholesterolemia in Patients with Suspected Heterozygous Familial Hypercholesterolemia Baylor IRB 014-122, Baylor Foundation, $3,100.00, status: closed 2014

G20) **McCullough PA,** overall study Principal Investigator and Study Chairman, Investigator Initiated Trial, "A Prospective, Double-blind, Placebo Controlled, Parallel Group, Randomized Trial of Extended Release Exenatide versus Placebo in Diabetic Patients with Type 4 Cardiorenal Syndrome: EXTEND-CRS", D5551L00004/ISSEXEN0013, FDA IND 123200, Baylor IRB 014-149, AstraZeneca, 2014, $1,597,901.93, status: open

G21) **McCullough PA**, overall study Principal Investigator, Iso-osmolar Contrast and the Timing of Coronary Angiography in the Multivariate Risk for Cardiac Surgery Associated with

Acute Kidney Injury and Major Adverse Renal and Cardiac Events (MARCE), Baylor IRB 014-096, GE Healthcare, Inc, 2015, $145,885.00, status open

G22) **McCullough PA**, overall study Principal Investigator, Timing of coronary angiography and multivariate risk for cardiac surgery associated acute kidney injury and major adverse renal and cardiac events (MARCE), Baylor IRB 014-096, Baylor Foundation, $8,100.00, status: closed 2016

G23) Mendez J, **McCullough PA**, et al, co-investigator, Assessment of Multiple Blood Biomarkers in Patients with Advanced Heart Failure Undergoing Evaluation for Cardiac Transplantation and Mechanical Circulatory Support, Baylor IRB 014-300, Critical Diagnostics, Inc, $10,400.00, status: closed 2016

G24) Bottiglieri, T, **McCullough PA**, et al, co-investigator, Urinary 11dhTxB2 response to acetylsalicylic acid (aspirin) in cardiovascular disease progression and adverse outcomes, Baylor IRB 008-230, Corgenix, Inc., $99,087.00, status: closed 2016

G25) Schussler JM, Vasudevan A, **McCullough PA**, co-investigator, Clinical outcomes and metabolomic and damage associated molecular patterns of acute kidney injury in patients undergoing percutaneous coronary intervention via the radial versus femoral artery approach, Baylor IRB 014-299, Baylor Health Care System Foundation, $61,416.00, status: closed 2018

G26) Tecson K, **McCullough PA**, coinvestigator, Contribution of Chronic Kidney Disease and Acute Kidney Injury to Heart Failure Outcomes, Baylor IRB 015-296, Baylor Health Care System Foundation, $43,424.60, status: open

G27) Vasudevan A, **McCullough PA**, coinvestigator, Burden of Cardiovascular Events Follow Percutaneous Coronary Intervention, Baylor IRB 015-297, Baylor Health Care System Foundation, $40,000.00, status: closed 2018

G28) Tecson, K, **McCullough PA**, Therapeutic Intensity of Lipid Lowering Therapy in Response to Recurrent Cardiovascular Events, Baylor IRB 017-106, Amgen, Inc., $249,990.00 status: open

G29) **McCullough PA**, Principal Investigator, A Case Finding Study of Familial Chylomicronemia, Akcea Pharmaceuticals, $10,000.00, status: closed 2017

G30) **McCullough PA**, Bottiglieri T, Tecson K. Baylor Foundation $49,923.80. Identifying metabolomic profiles among genetically confirmed familial hypercholesterolemia, dyslipidemia without familial hypercholesterolemia, and healthy controls, status start-up 2019

Site Principal Investigator Contracts

G1) Jafri S, **McCullough PA**, and the WATCH Investigators. Warfarin and Antiplatelet Therapy in Chronic Heart Failure, (W.A.T.C.H.) Field Center, Veterans Administration Cooperative Studies Program and Sanofi Pharmaceuticals, $36,000.00 (HFHS Grant #B51008) status: closed 2000

G2) Jafri S, **McCullough PA**, and the CHARM Investigators. Candesartan Cilexetil (Candesartan) in Heart Failure Assessment of Reduction in Mortality and Morbidity (C.H.A.R.M.) Field Center, 1999-2000, Astra Pharmaceuticals, $56,000.00 (HFHS Grant #E09045) status: closed 2000

G3) Schuger C, **McCullough PA**, and the MADIT Investigators. Multicenter Automatic Defibrillator Implantation Trial II (M.A.D.I.T.-II), Guidant Corporation/Cardiac Pacemakers (CPI), $96,000 (HFHS Grant #G10087) status: closed 2000

G4) Schuger C, **McCullough PA**, and the MIRACLE Investigators. Multicenter InSync Randomized Clinical Evaluation (M.I.R.A.C.L.E.), Medtronic Inc., $195,000, (HFHS Grant #G12006) status: closed 2000

G5) **McCullough PA,** Shetty A, Soman S and the CHORUS Investigators. Cerivastatin Heart Outcomes in Renal Disease: Understanding Survival (C.H.O.R.U.S.), Barry Brenner, MD and William F. Keane, MD, Co-Principal Investigators, Bayer Inc., 2000-2003 (RCT), Clinical Site Contract, Bayer Pharmaceuticals, $266,875.00 10% FTE (HFHS Grant #E05046) status: closed 2000

G6) **McCullough PA,** Manley HJ and the CHORUS Investigators. Cerivastatin Heart Outcomes in Renal Disease: Understanding Survival (C.H.O.R.U.S.), Barry Brenner, MD and William F. Keane, MD, Co-Principal Investigators, Bayer Inc., 2000-2003 (RCT), Clinical Site Contract, Bayer Pharmaceuticals, $279,000 10% FTE (UMKC Grant #E05046) status: closed 2001

G7) Nowak R, McCord J, **McCullough PA** and the BNP Investigators. Breathing Not Properly Study (B.N.P. Multinational Study), Alan Maisel, MD, and Peter A. McCullough, MD, MPH, Co-Principal Investigators, Biosite Diagnostics, Inc., (prospective cohort study) Field Center Contract, Biosite Diagnostics, Inc., $180,000.00 (HFHS Site), $500,000.00, 0% FTE (HFHS Grant #E03005) status: closed 2001

G8) Ehrman JK, **McCullough PA.** A Prospective Randomized Trial of a Personal Health Assistant in the Secondary Prevention of Heart Disease. Merck, Inc., $220,961.00, 7% FTE (HFHS Grant #E41010) status: closed 2002

G9) **McCullough PA** and the CORC Investigators. Kansas City Cardiomyopathy Questionnaire Interpretability Study, John A. Spertus, MD, MPH, Principal Investigator, Cardiovascular Outcomes Research Consortium (C.O.R.C.), 2001 (multicenter, U.S., prospective cohort study), $21,400.00, status: closed 2002

G10) **McCullough PA**, Rutherford BD, and the OAT Investigators. Occluded Artery Trial, Judith Hochman, MD, and Gervasio Lamas, MD, Co-Principal Investigators, National Institutes of Health, National Heart Lung and Blood Institute, $54,000.00. 0% FTE (UMKC Grant #K531122) status: closed 2002

G11) **McCullough PA** site Principal Investigator and National Executive Committee Member. Rapid Emergency Department Heart Failure Outpatient Trial, Biosite Diagnostics, $21,000. 0% FTE (UMKC Grant #K531130) status: closed 2002

G12) **McCullough PA** site Principal Investigator. African-American Heart Failure Trial (AHEFT). A Placebo-Controlled Trial of BiDil added to Standard Therapy in African American Patients with Heart Failure, NitroMed, Inc., $20,000.00 (UMKC Proposal #9722, TMC Grant #261231) status: closed 2002

G13) **McCullough PA** and the IMAGING Investigators for Cardiology Clinical Studies, LLC. Investigation of Myocardial Gated SPECT Imaging as Initial Strategy in Heart Failure: The IMAGING in Heart Failure Trial, Dupont Pharmaceuticals Inc., $20,000.00 (UMKC Proposal #9825, UMKC Grant #KG001278) status: closed 2002

G14) **McCullough PA**, site Principal Investigator, and Ad Hoc Executive Committee Member. Heart Failure and a Controlled Trial Investigating Outcomes of Exercise Training. National Institutes of Health, National Heart, Lung, and Blood Institute, subcontracted through the Duke Clinical Research Institute, $665,000, (NIH Grant #1 U01 HL63747 01A2, WBH Grant # RC 08-94837, Site #301) status: closed 2005

G15) **McCullough PA**, site Principal Investigator, and Executive Committee Member. Protocol No. 704.351 Evaluation of Synergy between Natrecor and Furosemide on Renal and Neurohormone Responses in Chronic Heart Failure: A Phase IV Study, Scios Inc., 2003 (multicenter, U.S., randomized cross-over trial), $105,447.50, (WBH Grant # RC 08-94836) status: closed 2005

G16) **McCullough PA,** site Principal Investigator and National Co-Principal Investigator. Protocol No. CCIB002FUS12. A Multicenter, Double-blind, Randomized, Parallel Group Study to Evaluate the Effects of Lotrel and Lotensin HCT on Microalbuminuria in Mild to Moderate Hypertensive Subjects with Type 2 Diabetes Mellitus, Novartis Inc., (multicenter, U.S., randomized trial), $63,649.90, (WBH Grant #RC 08-94838) status: closed 2006

G17) **McCullough PA,** and the ACCOMPLISH Investigators. Protocol No. CCIB002.12301. Avoiding Cardiovascular Events through Combination Therapy in Patients Living with Systolic Hypertension, Novartis, Inc., 2003 (multicenter, multinational, randomized trial) $159,241.00, (WBH Grant #RC 08-94844) status: closed 2006

G18) **McCullough PA**, site Principal Investigator. Efficacy of Vasopressin Antagonism in Heart Failure: Outcome Study with Tolvaptan, Protocol #156-03-236, IND #50,533, Otsuka Maryland Research Institute, (multicenter, international, randomized trial), $210,750.00, (WBH Grant #RC 08-94842 changed to #RC 08-94849) status: closed 2005

G19) **McCullough PA,** site Principal Investigator. A Multicenter, Double-Blind, Randomized, Parallel Group, 6-week Study to Evaluate the Efficacy and Safety of Ezetimibe/Simvastatin Combination versus Atorvastatin in Patients with Hypercholesterolemia, Protocol #051/EZT544, Merck, Inc., (multicenter, U.S., randomized trial), $18,840.00, (WBH Grant #RC 08-94843) status: closed 2006

G20) **McCullough PA,** site Principal Investigator, A multicenter, double-bind randomized, parallel-group study to compare the effect of 24 weeks treatment with LAF237 (50 mg qd or bid) to placebo as add-on therapy in patients with type 2 diabetes inadequately controlled with metformin monotherapy. Novartis Pharmaceuticals, Inc., (multicenter, U.S., randomized trial), $30,700.00, (WBH Grant #RC 08-94845) status: closed 2007

G21) **McCullough PA,** site Principal Investigator. A multicenter, double-bind randomized, parallel-group study to compare the effect of 24 weeks treatment with LAF237 (50 mg qd or bid) to placebo as add-on therapy to pioglitazone 45 mg qd in patients with type 2 diabetes inadequately controlled with thiazolidinediones monotherapy. Novartis Pharmaceuticals, Inc., (multicenter, U.S., phase III randomized trial) $30,700.00, (WBH Grant #RC 08-94846) status: closed 2006

G22) **McCullough PA,** site Principal Investigator. An 8-week, randomized, double-blind, parallel group, multicenter placebo and active controlled disease escalation study to evaluate the safety and efficacy of aliskiren in patients with hypertension, $47,100.00 (WBH #RC 08- 94852) status: closed 2007

G23) **McCullough PA,** site Principal Investigator. A randomized, double-blind study to compare the durability of glucose lowering and preservation of pancreatic beta-cell function of rosiglitazone monotherapy compared to metformin or glyburide/glibenclamide in patients with drug naïve, recently diagnosed type 2 diabetes, $140,100.00, Novartis Pharmaceuticals (WBH #RC 08-94849) status: closed 2008

G24) **McCullough PA,** site Principal Investigator. A multicenter, randomized, double-blind factorial study of the co-administration of MK-0431 and metformin in patients with type 2 diabetes who have inadequate glycemic control, $36,735.00, Merck Research Laboratories (WBH #RC 08-94853) status: closed 2008

G25) **McCullough PA**, site Principal Investigator. Multicenter, Randomized, Double-Blind Study to Evaluate the Efficacy & Safety of Ezetimibe/Simvastatin and Niacin Co-Administered in Patients with type IIa or Type IIb Hyperlipidemia, $46,960.00, Merck Research Laboratories, MRK-091, (WBH #RC 08-94854) status: closed 2008

G26) **McCullough PA,** site Principal Investigator. A Multi-Center, Randomized, Double-Blind, factorial Design study to evaluate the lipid-altering efficacy & safety of MK-0524B Combination Tablet in Patients with Primary Hypercholesterolemia or Mixed Hyperlipidemia $40,849.00, Merck Research Laboratories, MRK-022. (WBH #RC 08-94855) status: closed 2007

G27) **McCullough PA,** site investigator. An 8-week, multicenter, randomized, double-blind, parallel-group study to evaluate the efficacy and safety of the combination of valsartan/HCTZ/amlodipine compared to valsartan/HCTZ, valsartan/amlodipine, and HCTZ/amlodipine in patients with moderate to severe hypertension, $43,500.00, Novartis Pharmaceuticals (WBH #RC 08-94857) status: closed 2007

G28) **McCullough PA,** site Principal Investigator. A multicenter randomized, double-blind parallel arm, 6-week study to evaluate the efficacy and safety of ezetimibe/simvastatin versus atorvastatin in patients with metabolic syndrome and hypercholesterolemia at high risk for coronary heart disease, $32,010.00. Merck Research Laboratories (WBH #RC 08-94861) status: closed 2008

G29) **McCullough PA,** site Principal Investigator. A multicenter, randomized, double-blind study to evaluate the safety and efficacy of the initial therapy with coadministration of sitagliptin and pioglitazone in patients with type 2 diabetes mellitus, $24,036.00, Merck Research Laboratories, MRK-064 (WBH #RC 08-94860) status: closed 2008

G30) Dixon, SD, site PI, **McCullough PA**, Multinational Executive Committee. RENAL GUARD Pilot Trial. PLC Medical Systems, $37,610.00 (WBH #RC- 90771) status: closed 2008

G31) **McCullough, PA**, site Principal Investigator, A multi-center, randomized, double-blind, placebo and active controlled, parallel group, dose range study to evaluate the efficacy and safety of LCZ696 comparatively to valsartan, and to evaluate AHU377 to placebo after 8-week treatment in patients with essential hypertension. Novartis, Inc., $31,965.28. (WBH #RC-94863) status: closed 2008

G32) **McCullough PA,** site Principal Investigator. Paricalcitol capsules benefits in renal failure induced cardiac morbidity in subjects with chronic kidney disease stage 3b/4, (PRIMO Abbott Laboratories, ABT-M-10-030, $157,992.00, (WBH #RC-94864) status: closed 2008

G33) **McCullough PA,** site Principal Investigator. A randomized, double-blind, parallel group study to evaluate the effects of high-dose statin therapy on fluorodeoxyglucose (FDG) uptake in arteries of patients with atherosclerotic vascular disease. Merck Research Laboratories, MRK-081, $86,994.00 (WBH #RC 08-90223) status: closed 2008

G34) **McCullough PA,** site Principal Investigator. Patient registry for the Liposorber LA-15 system. Kaneka, Inc., $7,515.00, (WBH #RC-90877) status: closed 2009

G35) **McCullough PA,** site Principal Investigator. A 30-week multicenter, randomized, double-blind. Parallel-group study of the combination of ABT-335 and Rosuvastatin compared to rosuvastatin monotherapy in dyslipidemic subjects with stage 3 chronic kidney disease, Abbott M10-313, $128,544.00, (WBH #RC-90212) status: closed 2009

G36) **McCullough PA,** site Principal Investigator. A multicenter, randomized open label, active-comparator controlled study to assess the efficacy, safety, and tolerability of taspoglutide compared to exenatide in patients with type 2 diabetes mellitus inadequately controlled with metformin, thiazolidinedione, or a combination of both, Roche BC 21625, $72,012.50, (WBC #RC-90245) status: closed 2010

G37) **McCullough PA,** site Principal Investigator. A multicenter, randomized double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of taspoglutide compared to placebo in obese patients with type 2 diabetes mellitus inadequately controlled with metformin monotherapy, Roche BC 22092, $38,387.50, (WBH #RC-90258) status: closed 2009

G38) **McCullough PA,** site Principal Investigator. A safety and efficacy trial evaluating the use of apixaban for the extended treatment of deep vein thrombosis and pulmonary embolism, Bristol Myers Squibb-Pfizer CV185057, $173,750.00, (WBH #RC-90288) status: closed 2009

G39) **McCullough PA,** site Principal Investigator. A phase 3, active (warfarin) controlled, randomized, double-blind, parallel arm study to evaluate efficacy and safety of apixaban in preventing stroke and systemic embolism in subjects with nonvalvular atrial fibrillation, Bristol Myers Squibb-Pfizer CV1805030, $173,750.00, (WBH #RC-90275) status: 2009

G40) **McCullough PA,** site Principal Investigator. Treatment of Preserved Cardiac Function Heart Failure with an Aldosterone Antagonist Trial (TOPCAT), National Institutes of Health, National Heart, Lung, and Blood Institute, subcontracted through the New England Research Institutes, Inc., $86,250.00, (WBH #RC-90267) status: closed 2010

G41) **McCullough PA,** site Principal Investigator. An 8-week, randomized, double-blind, parallel group, multicenter, forced titration study to evaluate the efficacy and safety of aliskiren plus HCTZ verus aliskiren monotherapy in metabolic syndrome patients with stage 2 hypertension, Novartis, Inc., $107,362.44 (WBH #RC-90277) status: closed 2009

G42) **McCullough PA**, site Principal Investigator, Astute SAPPHIRE AST-111, Evaluation of Novel Biomarkers from Acutely Ill Patients at Risk for Acute Kidney Injury, Astute Medical, Inc, San Diego, CA, $23,195.50 status: closed 2012

G43) **McCullough PA**, site Principal Investigator, protocol number 156-10-292 titled "An Observational Prospective Registry to Identify Demographic and Clinical Characteristics of Patients Hospitalized with Euvolemic and Hypervolemic Hyponatremia and Assess the Comparative Effectiveness of Available Treatments and the Impact on Resource Utilization. Otsuka Inc., $21,262.60 status: initial contract fulfilled, reopened under extension and registry completed in 2013

G44) **McCullough PA**, site Principal Investigator, PROspective Multicenter Imaging Study for Evaluation of Chest Pain (PROMISE) Study, National Heart, Lung, and Blood Institute (NHLBI), Pamela Douglas, MD, Principal Investigator Clinical Coordinating Center, Duke Clinical Research Institute, $17,000.00 status: closed 2012

G45) **McCullough PA**, site Principal Investigator, ACZ885M/Canakinumab Clinical Trial Protocol CACZ885M2301 A randomized, double-blind, placebo-controlled, event-driven trial of quarterly subcutaneous canakinumab in the prevention of recurrent cardiovascular events among stable post-myocardial infarction patients with elevated hsCRP. Novartis, Inc., 2011 $279,223.00 status: closed 2015

G46) **McCullough PA**, site Principal Investigator, AN-CVD2233 Evaluation of the Safety and Efficacy of Short-term A-002 (Varespladib) Treatment in Subjects with Acute Coronary Syndromes (VISTA-16) Anthera Pharmaceuticals, Inc., 2011 $72,600.00 status: closed 2011

G47) **McCullough PA**, site Principal Investigator, BC22140A Cardiovascular outcomes study to evaluate the potential of aleglitazar to reduce cardiovascular risk in patients with a recent acute coronary syndrome (ACS) event and type 2 diabetes mellitus (T2D), F. Hoffmann-La Roche Ltd, $307,500.00 status: closed 2012

G48) **McCullough PA**, site Principal Investigator, A Double-blind, Randomized, Placebo-controlled, Multicenter Study (Phase 2) to Evaluate the Safety and Efficacy of IV Infusion Treatment with Omecamtiv Mecarbil in Subjects with Left Ventricular Systolic Dysfunction Hospitalized for Acute Heart Failure (Protocol 20100754), Amgen, Inc, 253,464.00 status: closed 2012

G49) **McCullough PA**, site Principal Investigator, MB102-073 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Dapagliflozin in Subjects with Type 2 Diabetes with Inadequately Controlled Hypertension on an Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB), Bristol-Myers Squibb Research and Development, 2011 $34,115.00 status: closed 2012

G50) **McCullough PA,** site Principal Investigator, MB102-077 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Dapagliflozin in Subjects with Type 2 Diabetes with inadequately controlled hypertension treated with an Angiotensin-Converting Enzyme Inhibitor (ACEI) or

Angiotensin Receptor Blocker (ARB) and an additional Antihypertensive medication, Bristol-Myers Squibb Research and Development, $34,115.00 status: closed 2011

G51) **McCullough PA**, site Principal Investigator, ABT M11350 RADAR: Reducing Residual Albuminuria in Subjects with Diabetes and Nephropathy with AtRasentan – A Phase 2b, Prospective, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate Safety and Efficacy, Abbott Laboratories, $188,377.00 status: closed 2012

G52) **McCullough PA**, site Principal Investigator, PEGASUS TIMI 54 trial, A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to Assess the Prevention of Thrombotic Events with Ticagrelor Compared to Placebo on a Background of Acetyl Salicylic Acid (ASA) Therapy in Patients with History of Myocardial Infarction, AstraZeneca, 2011 $98,530.00 status: transferred to PI Marcel Zughaib, MD

G53) **McCullough PA**, site Principal Investigator, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease AMG 145 Amgen Protocol Number 20110118 EudraCT number 2012-001398-97, Amgen, Inc., $1,732,062.80 status: closed 2016

G54) **McCullough PA,** site Principal Investigator, A single-blind, multi-site trial of the dietary supplement anatabine (RCP006) to determine the effects on peripheral markers of inflammation in patients with elevated levels of C-reactive protein (CRP). Roskamp Institute Protocol Number RI-11-01, $6700.00 status: closed 2012

G55) **McCullough PA**, site Principal Investigator, Long-term safety and tolerability of REGN727/SAR236553 in high cardiovascular risk patients with hypercholesterolemia not adequately controlled with their lipid modifying therapy: a randomized, double-blind, placebo-controlled study LTS11717 Sanofi Aventis, $252,000.00 status: closed 2013

G56) **McCullough PA**, site Principal Investigator, Assessment of Clinical Effects of Cholesteryl Ester Transfer Protein Inhibition with Evacetrapib in Patients at a High Risk for Vascular Outcomes – the ACCELERATE Study, protocol I1V-MC-EIAN, Eli Lilly, $421,202.00 status: closed 2014

G57) **McCullough PA,** site Principal Investigator, AEGR-733-025, LOWER: Lomitapide Observational Worldwide Evaluation Registry, Aegerion, Inc., 2014, $23,478.00 status: open

G58) **McCullough PA**, site Principal Investigator, The Evaluation Of PF-04950615 (RN316), In Reducing the Occurrence of Major Cardiovascular Events in High Risk Subjects (SPIRE-1), Pfizer, Inc., $145,343.90 status: closed 2016

G59) **McCullough PA**, site Principal Investigator, The Evaluation Of PF-04950615 (RN316) In Reducing the Occurrence of Major Cardiovascular Events in High Risk Subjects (SPIRE-2), Pfizer, Inc., $145,343.90 status: closed 2016

G60) **McCullough PA,** site Principal Investigator, Long Term Observational Study in Patients with Homozygous Familial Hypercholesterolemia Treated with Kynamaro™, Genzyme-Sanofi, Inc., $61,260.00 status: closed 2018

G61) **McCullough PA**, site Principal Investigator, CUP14366, Alirocumab (SAR236553) Expanded Access Program for the Treatment of Severe Hypercholesteremia Not Controlled with Maximal Tolerated Dose of Lipid Lowering Therapy Administered According to Standard of Care, Sanofi-Regeneron, Inc., 2015 $8,500.00 status: closed 2015

G62) **McCullough PA,** site Principal Investigator, Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE), Patient-Centered Outcomes Research Institute, 2015 $29,400.00 status: open

G63) **McCullough PA**, site Principal Investigator, Assessment of Heart Failure using Condition-Specific Impact Assessments (PROMIS), Patient-Centered Outcomes Research Institute, 2015 $81,840.00 status: 2017 status: closed

G64) **McCullough PA**, site Principal Investigator, A Randomized Parallel-Group, Placebo-Controlled, Double-Blind, Event-Driven, Multi-Center Pivotal Phase III Clinical Outcome Trial of Efficacy and Safety of the Oral sGC Stimulator Vericiguat in Subjects With Heart Failure With Reduced Ejection Fraction (HFrEF) - VerICiguaT Global Study in Subjects With Heart Failure With Reduced Ejection Fraction (VICTORIA), Merck, Inc, 2017 $878,163.90 status: closed

G65) **McCullough PA**, site Principal Investigator, A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with preserved Ejection Fraction (HFpEF), EMPEROR-PRESERVED, Boehringer-Ingleheim, 2017 $170,099.00, status: open

G66) **McCullough PA**, site Principal Investigator, A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with preserved Ejection Fraction (HFpEF), EMPEROR-REDUCED, Boehringer-Ingleheim, 2017 $170,099.00, status: open

G67) Schiffmann R, **McCullough PA** Sub-Investigator, 014-097 PB-102-F03 (Sponsor - Protalix - PRX-102 1mg/kg q 2 weeks) A Multi Center Extension Study of PRX-102 Administered by Intravenous Infusions Every 2 Weeks for 60 Months to Adult Fabry Patients, status: open

G68) Schiffmann R, **McCullough PA** Sub-Investigator, 014-288 AT1001-042 (Sponsor - Amicus - oral drug - chaperone) An Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Migalastat Hydrochloride Monotherapy in Subjects with Fabry Disease, status: closed.

G69) Schiffmann R, **McCullough PA** Sub-Investigator, 016-153 PB-102-F20 (Sponsor - Protalix - BLINDED - ERT PRX-102 or Fabrazyme 1mg/kg q 2 weeks) A Randomized, Double blind, Active Control Study of the Safety and Efficacy of PRX-102 compared to Agalsidase Beta on Renal Function in Patients with Fabry Disease Previously Treated with Agalsidase Beta – Study Number PB-102-F20, status: open

G70) Schiffmann R, **McCullough PA** Sub-Investigator, 017-189 PB-102-F50 (Sponsor - Protalix - PRX-102 infusion - 2mg/kg monthly) A Phase 3, Open Label, Switch Over Study to Assess the Safety, Efficacy and Pharmacokinetics of pengunigalsidase alfa (PRX-102) 2 mg/kg Administered by Intravenous Infusion Every 4 Weeks for 52 weeks in Patients with Fabry Disease Currently Treated with Enzyme Replacement Therapy: Fabrazyme® (agalsidase beta) or Replagal (agalsidase alfa), status: open

G71) Schiffmann R, **McCullough PA** 018-150 MODIFY (Sponsor - Idorsia - oral drug - substrate reduction) A multicenter, double-blind, randomized, placebo controlled, parallel-group study to determine the efficacy and safety of lucerastat oral monotherapy in adult subjects with Fabry disease, status: open

G72) **McCullough PA**, site Principal Investigator, A Randomized, Double-blind, Placebo-controlled, Parallel-group Multicenter Study to Evaluate the Effects of Sotagliflozin on Clinical Outcomes in Hemodynamically Stable Patients with Type 2 Diabetes Post Worsening Heart Failure (SAR 439954), Sanofi US Services, Inc, $214,600.00, 2019, status: open

G73) **McCullough PA**, site Sub-Investigator, A Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Safety and Efficacy of Alirocumab in Patients with Homozygous Familial Hypercholesterolemia (R727-CL-1628), Regeneron Pharmaceuticals, Inc, $143,503.00, 2019, status: closed

G74) **McCullough PA**, site Sub-Investigator, A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Evinacumab in Patients with Homozygous Familial Hypercholesterolemia (R1500-CL-1629) Regeneron Pharmaceuticals, Inc, $143,503.00, 2019, status: closed

G75) **McCullough PA**, site Sub-Investigator, An Open-Label Study to Evaluate the Long-Term Efficacy and Safety of Evinacumab in Patients with Homozygous Familial Hypercholesterolemia (R1500-CL-1719) Regeneron Pharmaceuticals, Inc, $65,317.44, 2019, status: open

G76) Bottiglieri T, Tecson K, **McCullough PA**, Identifying metabolomic profiles among genetically confirmed familial hypercholesterolemia, dyslipidemia without familial hypercholesterolemia, and healthy controls, Baylor Health Care System Foundation, $49,293.80, 2020 status: open

G77) **McCullough PA**, Wheelan KE. BSWRI—Overall Principal Investigator, 001 A prospective clinical study of hydroxychloroquine in the prevention of SARS-COV-2 (COVID-19) infection in health care workers after high-risk exposures, FDA IND 149293, Baylor Health Care System Foundation, $506,506.00, 2020 status: open

G78) **McCullough PA**, Site Investigator, 4D-310-C001 entitled "An Open-label, Phase 1/2 Trial of Gene Therapy 4D-310 in Adult Males with Fabry Disease" 4D Molecular Therapeutics, Inc, $101,210.85, 2020 status: open

G79) **McCullough PA,** Site Investigator, TQJ230, Assessing the Impact of Lipoprotein (a) Lowering With TQJ230 on Major Cardiovascular Events in Patients With CVD (Lp(a)HORIZON) Novartis Pharmaceuticals Corporation, $3,475,000.00, 2020 status open

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A2) **McCullough PA**, O'Neill WW, Hoffman M, Glazier S, Safian RD. The "Protective Effect" of Restenosis Lesions on Angiographic Complications with New Devices. Circulation 1995;92:I-346 [poster].

A3) **McCullough PA**, Wolyn R, Rocher LL, Levin RN, O'Neill, WW. Acute Contrast Nephropathy After Coronary Intervention: Prediction of Dialysis and Related Mortality in the Elderly. American Journal of Geriatric Cardiology 1996;5:52 [poster].

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A5) **McCullough PA**, Ayad O, Goldstein JA. Cost-Effectiveness Analysis of Patients Admitted with Chest Pain and Normal or Near-Normal Electrocardiograms. Cathet Cardiovasc Diag 1996;38:118 [poster].

A6) Aliabadi D, **McCullough PA**, Kaplan B, Grines CL, Safian RD, Pica M, O'Neill WW, Goldstein JA. A Novel Mobile Fluoroscopic Imaging System for Rapid Bedside Coronary Angiography. Cathet Cardiovasc Diag 1996;38:111 [oral].

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A8) **McCullough PA**, O'Neill WW, Graham M, David S, Stomel R, Rogers F, Grines CL. A Prospective Randomized Trial of Triage Angiography in Suspected Acute Myocardial Infarction Patients Who are Considered Ineligible for Reperfusion Therapy. Circulation 1996;94:I-570 [oral].

A9) Aliabadi D, **McCullough PA**, Grines CL, Safian RD, Pica MC, O'Neill WW, Goldstein JA. A Novel Mobile Fluoroscopic Imaging System for Rapid Bedside Coronary Angiography. J Am Coll Cardiol 1997;450A [poster].

A10) **McCullough PA**, O'Neill WW, Graham M, David S, Stomel R, Rogers F, Farhat A, Kazlauskaite R, Grines CL. Late Outcomes in the Medicine vs. Angiography for Thrombolytic Exclusion (MATE) Study. Circulation, 1997;96:I-595-596 [oral].

A11) Redle JD, West AJ, Khurana S, Marzan R, **McCullough PA**, Frumin HI. Prophylactic Oral Amiodarone with Beta Blockade has Favorable Effects on Atrial Fibrillation Post Coronary Bypass Surgery. Circulation, 1997;96:I-125 [poster].

A12) Sharma ND, Gandhi RS, Philbin EF, Weaver WD, **McCullough PA**. Which Patients with Left Ventricular Dysfunction Require Chronic Anticoagulation? A Prospective Analysis. J Am Coll Cardiol 1998;31:33A. [poster].

A13) **McCullough PA**, Tobin KJ, Kahn JK, O'Neill WW, Thompson RJ. Prediction of In-hospital Survival after Sudden Cardiac Death: Derivation and Validation of a Clinical Model. J Am Coll Cardiol 1998;31:485A [poster].

A14) Stevens M, **McCullough PA**, Tobin KJ, Speck JP, Westveer DC, Guido-Allen DA, Hartenburg DS, Puchrowicz-Ochocki SB, O'Neill WW. A Randomized Trial of Prevention Measures in Patients at High Risk for Contrast Nephropathy: Initial Results of the PRINCE Study. J Am Coll Cardiol 1998;31:469A [poster].

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A16) **McCullough PA**, Al-Zagoum M, Graham M, David S, Stomel R, Rogers F, Farhat A, Kazlauskaite R, Grines CL, O'Neill WW. A Time to Treatment Analysis in the Medicine vs. Angiography for Thrombolytic Exclusion Trial. Cathet Cardiovasc Diag 1998;44:105 [oral].

A17) **McCullough PA**, Al-Zagoum M, O'Neill WW, Graham M, David S, Stomel R, Rogers F, Farhat A, Kazlauskaite R, Grines CL. A Program of Triage Angiography in Acute Coronary Syndromes Ineligible for Thrombolysis: An Efficacy Analysis. Cathet Cardiovasc Diag 1998;44:105[poster].

A18) Philbin EF, **McCullough PA**, Polanczyk CA, Jenkins PL, DiSalvo TG. Are Subjects in Heart Failure Trials Similar in Clinical Practice? Circulation, 1998;98:I-866 [moderated poster].

A19) **McCullough PA**, Smith S, Borzak S. Understanding the Risks Associated with Baseline Renal Function in the Coronary Care Unit. Circulation, 1998;98:I-413 [poster].

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A25) **McCullough PA,** Cingireddy U, Philbin EF, Weaver WD. Evidence for a Heart Failure Epidemic: Findings from the REACH Study. J Am Coll Cardiol 1999;33:179A [poster].

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A27) Hassan SA, Borzak S, Philbin EF, Soman S, Shah S, Weaver WD, Yee J, Marks KR, **McCullough PA**. The Impact Chronic Renal Insufficiency on Heart Failure Mortality after Hospitalization. Journal of Cardiac Failure 1999;5 Suppl 1:70. [poster].

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A30) **McCullough PA,** Prakash R, Tobin KJ, O'Neill WW, Thompson RJ. Application of a Cardiac Arrest Score in Patients with Sudden Death and ST Segment Elevation for Triage Angiography and Intervention. Fighting Sudden Cardiac Death: A Worldwide Challenge, 1999;18:T-2.

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T32) Rangaswami J, Lerma EV, **McCullough PA**, Editors. Kidney Disease in the Cardiac Catheterization Laboratory, 1st Edition 2020, ISBN-13: 978-3030454135 ISBN-10: 3030454134, Springer Nature Switzerland AG. Chapter 27 Ronco C, Ronco F, **McCullough PA**. A Call to Action to Develop Integrated Curricula in Cardiorenal Medicine, pp 449-463.

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Invited Non-Peer Reviewed Works

1) **McCullough PA**. *Acute Renal Failure after Coronary Intervention*. American College of Cardiology Educational Highlights, Fall 1997 Issue, C.R. Conti, Editor

2) **McCullough PA**, Thompson RJ, Tobin KJ, Kahn JK, Schwender F, O'Neill WW. *Outcome of Out-of-Hospital Cardiac Arrest Survivors.* Cardiology Review, 2000;17:15-19

3) Thompson RJ, **McCullough PA**, Kahn JK, O'Neill WW. *A Simple Scoring System to Predict Clinical Outcome after Resuscitation from Cardiac Arrest.* The Journal of Critical Illness, 1998;13:298-300

4) **McCullough PA.** *Clinical Evaluation. Part I. The Cardiopulmonary System.* Clinical Exercise Physiology, 1999;1:33-41

5) **McCullough PA.** *Clinical Evaluation. Part II. The Musculoskeletal and other Body Systems.* Clinical Exercise Physiology, 1999:1:92-99

6) **McCullough PA.** *Ridogrel: Literature Evaluation.* IDdb Reports, Current Drugs Ltd, February, 1999

7) **McCullough PA.** Debate Commentary: Complete Assessment of the Lipid Profile is Advised. Medical Crossfire, 1999:5;52

8) **McCullough PA.** Narrative Fields in Hospital Records. Invited comment on Loss of Narrative Data in New Zealand Health Statistics Public Hospital Injury Files, John Langley (Australasian Epidemiologist 1998:5.4). The Australasian Epidemiologist, 1999;6.1:17-18

9) **McCullough PA.** Previews in Cardiovascular Medicine: Prediction and Prevention of Contrast Nephropathy. Rev Cardiovasc Med. 2001;2(Suppl 1):S1-S3

10) Creager MA, Faxon DP, Fonarow GC, Gross SB, Hachamovitch R, Jacobs AK, Lepor NE, **McCullough PA**, Naqvi T, Nesto RW, Prystowsky EN, Shah PK, Vogel RA, Yeung AC. Meeting Reviews: Best of the AHA Scientific Sessions, 2001. Rev Cardiovasc Med. 2002;3(1):22-48

11) **McCullough PA**. Update from the International Society on Hypertension in Blacks. Rev Cardiovasc Med. 2002 Fall;3(4):192-95. PMID: 12650156

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13) Lepor NE, Yeung AC, **McCullough PA**, Creager MA, Weber MA, Jacobs AK, Faxon DP, Vogel RA, Gersh BJ. Meeting Review: Best of the ACC Scientific Session 2002. Rev Cardiovasc Med 2002;3(2):85-104

14) Franklin BA, deJong A, **McCullough PA**. Interpreting Exercise Test-Fitness Data for Your Patients. Am J Sports 2003;5:12-17

15) **McCullough PA.** The interface between heart disease and renal dysfunction: from association to action. ACC Current Journal Review 2003;12(2):20-24

16) Fonarow GC, Prystowsky EN, **McCullough PA**, Lepor NE, Watson KE, Gersh BJ, Young JJ, Kereiakes D, Faxon DP, Weyman A, Jacobs AK, Yeung A, Holmes D, Berger P, Weber MA. Meeting Review: Best of the ACC Scientific Sessions 2003. Rev Cardiovasc Med. 2003;4(3):150-179

17) **McCullough PA.** Debate Commentary: Atrial Fibrillation: Preventing Thromboembolism and Ischemic Stroke. Medical Crossfire 2003, 4(10), 3-17

18) Creager M, Faxon DP, Gersh BJ, Jacobs AK, Lepor NE, **McCullough PA,** Naqvi T, Prystowsky EN, Shah PK, Watson KE, Weber MA, Wyman A. Meeting Review: Best of the AHA Scientific Sessions 2003. Rev Cardiovasc Med 2004;5(1)26-52

19) **McCullough PA.** The use of contrast media in peripheral, combined, and sequential procedures. Applications in Imaging: Cardiac Interventions: Contrast Use in Renally Compromised Patients 2003;Sept:47-51

20) **McCullough PA.** Chapter Four: Major Risk Factors for Chronic Kidney Disease. Kidney Early Evaluation Program Annual Data Report. Am J Kid Dis 2003;42(5):S34-S41

21) Fonarow GC, Prystowsky EN, Lepor NE, Weyman AE, Weber MA, Watson KE, Young JJ, Kereiakes DJ, **McCullough PA,** Gersh BJ**.** Best of the ACC Scientific Session 2004. Rev Cardiovasc Med. 2004;5(2)104-129

22) Franklin BA, de Jong A, Kahn JK, **McCullough PA.** Fitness and mortality in the primary and secondary prevention of coronary artery disease: Does the effort justify the outcome? Am J Med Sports 2004;6:23-27

23) **McCullough PA**, Franklin BA. Atherosclerosis: Conventional risk factors and cardiac events—debunking an old myth about prevalence. Rev Cardiovasc Med. 2004;5(3):185-186

24) Dutcher JR, **McCullough PA**. Commentary: Glycoprotein IIb/IIIa Inhibitors in Acute Coronary Syndromes. Evidenced Based Cardiovascular Medicine 2004;8:362-363

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28) **McCullough PA**. Clinical utility of blood natriuretic peptide levels. Business Briefing: US Cardiology 2006. Touch Briefings, Touch Cardiology. www.touchcardiology.com

29) **McCullough PA**, Wase A. Do implantable cardioverter-defibrillators improve survival in dialysis patients after cardiac arrest? Nature Clinical Practice Nephrology 2006; 2(2): 70-71

30) **McCullough PA.** Ranolazine: focusing on angina pectoris. Drugs of Today 2006, 42 (3):177-183

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32) **McCullough PA.** Safety Concerns Trump Public Health Benefit in the Eyes of the FDA Cardiorenal Panel. FDA Advisory Committee Did Not Recommend Approval Of Rimonabant (ZIMULTI(R)) For Use In Obese And Overweight Patients With Associated Risks Factors. www.medicalnewstoday.com GLG NewsWatch for 6/14/2007

33) Friedewald VE, Goldfarb S, Laskey WK, **McCullough PA**, Roberts WC. The Editor's Roundtable: Contrast-Induced Nephropathy. Am J Cardiol. 2007 Aug 1;100(3):544-51. Epub 2007 Jun 4. PMID: 17659944

34) **McCullough PA**, Lepor NE. Erratum - the rosiglitazone meta-analysis. Rev Cardiovasc Med. 2007 Summer;8(3):174. PMID: 17938618

35) **McCullough PA,** Chronic Kidney Disease as a Cardiovascular Risk State and Considerations for the Use of Statins. The Fats of Life, Lipoproteins and Vascular Disease Division, American Association of Clinical Chemistry, Volume XXII, No 1, 9-16 Winter 2008

36) Lepor NE, **McCullough PA**, Jacobs AK. Best of the AHA Scientific Sessions 2007. Rev Cardiovasc Med. 2008 Winter;9(1):62-9. PMID: 18418310

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38) Narala KR, LaLonde TA, Hassan S, **McCullough PA**. Management of Chronic Coronary Disease and Acute Coronary Syndromes in Patients with Chronic Kidney Disease. US Cardiology, 2011;8(2):123-31

39) Larsen T, Narala KR, **McCullough PA.** Type 4 Cardiorenal Syndrome: Myocardial Dysfunction, Fibrosis, and Heart Failure in Patients with Chronic Kidney Disease. J Clinic Experiment Cardiol 2012, 3:4. http://dx.doi.org/10.4172/2155-9880.1000186

INVITED LECTURES: NATIONAL AND INTERNATIONAL FORUMS

L1) "The Role of Triage Angiography in Acute Coronary Syndromes." Advances in Interventional Cardiology. WBH and the University of Maryland, Aruba, April, 1997.

L2) "New Understandings of Anticoagulation During Unstable Angina." Co-Chair, American College of Cardiology 47th Annual Scientific Session, Atlanta, Georgia, March 30, 1998.

L3) National Library of Medicine: The Emerging Health Information Infrastructure '99. "Electronic Outcomes", Washington, D.C., April 28, 1999.

L4) Kansas City Southwest Clinical Society, 77th Annual Clinical Conference, Overland Park, Kansas: "Cardiac-Renal Risk: Incorporating Scientific Evidence into Your Practice," October 29, 1999.

L5) The Health Forum, Best Practices, Chicago, Illinois. "Overview of Cardiovascular Health Fellowship," December 9, 1999.

L6) AHA Scientific Conference on Existing Databases: Do They Hold Answers to Clinical Questions in Geriatric Cardiovascular Disease and Stroke? "Resource Utilization Among Congestive Heart Failure (R.E.A.C.H.) Database Overview," Washington, DC, January 27, 2000.

L7) Health Forum Cardiovascular Health Fellowship Retreat: "Cardiovascular Risk and Health," Colorado Springs, CO, July 20, 2000.

L8) Third Annual Center for Health Futures Advisory Board Meeting: "Congestive Heart Failure," La Jolla, CA, August 24, 2000.

L9) Health Forum ACT Learning Collaborative Meeting: "Bridging Clinical, Community, and Population Health Strategies," St. Joseph, MO, September 20, 2000.

L10) "Renal Disease as an Independent Risk Factor for Cardiovascular Disease in Diabetes," The Nexus of Cardiovascular and Renal Disease, Duke Clinical Research Institute, Tyson's Corner, VA, November 4, 2000.

L11) "Atherosclerosis and Heart Disease," Winter Scientific Seminar, Missouri Society of the American College of Osteopathic Physicians, Kansas City, MO, January 27, 2001.

L12) "Routine vs Selective Intervention in Acute Coronary Syndromes," Tenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 14, 2001.

L13) "Intervention in the Patient with Renal Insufficiency," Tenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 16, 2001.

L14) "The Epidemic of Cardiovascular Disease and Cardiorenal Risk," The Nexus of Cardiovascular and Renal Disease, Duke Clinical Research Institute, Tyson's Corner, VA, February 24, 2001.

L15) "Cardiovascular Risk in Chronic Kidney Disease: Cardiorenal Risk," Symposium on Cardio-renal Consequences of Angiotensin II, Insights from AII Blockade, NKF Spring Clinical Meeting, Orlando, FL, April 18, 2001.

L16) Plenary Session: "Cardiac Emergencies and Cardiac Critical Care," American College of Chest Physicians, CHEST 2001, Philadelphia, PA, November 5, 2001.

L17) "Cardiorenal Risk," The 33rd Annual ACC Cardiovascular Conference at Snowmass, Snowmass, Colorado, January 18, 2002.

L18) "Epidemiology of Diabetes and Its Cardiovascular Risk" Eleventh Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 14, 2002.

L19) "Late-Breaking Clinical Trials II: A Prospective, Blinded Trial of B-Type Natriuretic Peptide as a Diagnostic Test for the Emergency Diagnosis of Heart Failure: The Breathing Not Properly (BNP) Multinational Study," March 19, 2002, 51st Annual Scientific Session of the American College of Cardiology, Atlanta, GA.

L20) "Scope of Cardiovascular Complications in Patients with Kidney Disease." Plenary Session III: Reversing Cardiovascular Complications in Patients with Kidney Disease. International Society on Hypertension in Blacks: 17th International Interdisciplinary Conference on Hypertension and Related Risk Factors in Ethnic Populations, Miami, FL, June 11, 2002.

L21) "Epidemiology: Renal—Chronic Kidney Disease." Atherosclerotic Vascular Disease Conference, AHA, Boston, MA, July 8, 2002.

L22) "B-type Natriuretic Peptide Should be a Part of the Diagnostic Evaluation of Heart Failure: Implications from the Breathing Not Properly (BNP) Multinational Study" International Academy of Cardiology 8th World Congress on Heart Failure—Mechanisms and Management, Washington, DC, July 15, 2002.

L23) "Epidemiology and Physiology of Radiocontrast Nephropathy and its Impact on Outcomes" Prevent the Event Transcatheter Therapeutics 2002 Satellite Symposium, Washington, DC, September 26, 2002.

L24) "Calcification or 'Phosphication'—Controversies of Calcium Phosphate Deposition: Invited Lecture: Coronary Calcification: A Predictor of Future Events or a Marker of Plaque Stability? American Society of Nephrology 2002 Annual Scientific Sessions Satellite Symposium, Philadelphia, PA, November 1, 2002.

L25) "Renal Insufficiency and Clinical Outcome" Cardiovascular Seminar, AHA Scientific Sessions, Chicago, IL, November 18, 2002.

L26) "Role of BNP in the Diagnosis of Heart Failure" ACC 34th Annual Cardiovascular Conference at Snowmass, CO, January 14, 2003.

L27) "Managing the Patient with Combined Heart and Renal Failure—the Importance of Anemia" ACC 34th Annual Cardiovascular Conference at Snowmass, CO, January 14, 2003.

L28) "The Emerging Healthcare Crisis of Obesity," Twelfth Annual Cardiovascular Conference at Beaver Creek, CO, February 10, 2003.

L29) "BNP in the Management of Heart Failure," Twelfth Annual Cardiovascular Conference at Beaver Creek, CO, February 11, 2003.

L30) "Contrast Nephropathy: Can it be Eliminated," Twelfth Annual Cardiovascular Conference at Beaver Creek, CO, February 13, 2003.

L31) "How Subtle Degrees of Renal Dysfunction Work as a Cardiac Risk Factor" First Cardiovascular Prevention Symposium: Updates and New Guidelines. AHA, Puerto Rico Chapter, San Juan, PR, March 22, 2003.

L32) "What Is the Incremental Diagnostic Value of B-Type Natriuretic Peptide in Heart Failure?" Symposium. American College of Cardiology Scientific Sessions, 2003, Chicago, IL, April 1, 2003.

L33) "Heart Failure Insights From Ejection Fraction" Session Co-Chair. Oral Contributions. American College of Cardiology Scientific Sessions, 2003, Chicago, IL, April 1, 2003.

L34) "Chronic Renal Insufficiency as a Vascular Risk Factor" 14th Annual Scientific Sessions of the Society for Vascular Biology and Medicine, Chicago, IL, June 7, 2003.

L35) "Phosphate Control and Calcification from a Cardiologist's Perspective" World Congress of Nephrology Satellite Symposium, Berlin, Germany, June 12, 2003.

L36) "Renal Disease is a Risk Factor for Cardiovascular Disease" ACC 29th Annual Tutorials in the Tetons 2003: Update in Cardiovascular Disease, August 25-27. 2003.

L37) "Diagnosis of Congestive Heart Failure: Is BNP Needed in Every Case?" ACC 29th Annual Tutorials in the Tetons 2003: Update in Cardiovascular Disease, August 25-27. 2003.

L38) "How to Treat Combined Heart and Renal Failure with Hypertension" ACC 29th Annual Tutorials in the Tetons 2003: Update in Cardiovascular Disease, August 25-27. 2003.

L39) "Which Agents Prevent Contrast-Induced Nephropathy?" European Society of Cardiology 2003 Symposium: Managing Patients at Risk for Contrast-Induced Nephropathy, Vienna, Austria, September 2, 2003.

L40) "Epidemiology of Contrast Nephropathy" Symposium Chair for "A Contrast in Risk: Radiographic Imaging in the Renally Compromised Patient", Satellite Symposium at the Transcatheter and Therapeutics Scientific Meeting, Washington, DC, September 17, 2003.

L41) "Update on Cardiovascular Risk Reduction in Acute Coronary Syndrome Patients" 14th Annual Great Wall International Congress of Cardiology, Beijing, China, October 10-13, 2003.

L42) "Renal Function and Dysfunction in Coronary Arteriography" 14th Annual Great Wall International Congress of Cardiology, Beijing, China, October 10-13, 2003.

L43) "Interventional Cardiology 2003: Bench to Bedside and Beyond, Session III: Contrast Nephropathy: Separating the Hype from the Data. Antagonist: Contrast Nephropathy Can be Prevented." AHA Scientific Sessions 2003, November 9, 2003, Orlando, FL.

L44) "Reversing Diabetes and Its Consequences: Pipe Dream or Reality?" The 35th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 12-16, 2004.

L45) "Refining the Use of B-type Natriuretic Peptide as a Diagnostic Test in Clinical Practice" The 35th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 12-16, 2004.

L46) "Practical Management of Obesity for the Cardiologist: The Future of Dietary Management and Bariatric Surgery" The 35th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 12-16, 2004.

L47) "Update from the Hypertension World: JNC 7—What's New and How Will it Influence Practice?" Thirteenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 9-13, 2003

L48) "The Lethal Couplet" Thirteenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 9-13, 2003

L49) "BNP to Differentiate Between Cardiac and Extracardiac Sources of Dyspnea" 33rd Critical Care Congress, Society of Critical Care Medicine, Orlando, Florida, February 23, 2004.

L50) "BNP Testing: Is It Ready for In-Hospital Monitoring of Therapy?" Point-of-Care Symposium, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 8, 2004.

L51) "Role of Brain Natriuretic Peptide Levels in Diagnosis" Natriuretic Peptides Symposium, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 8, 2004.

L52) "Renal Insufficiency and the Heart" Symposium Co-Chair, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 9, 2004.

L53) "Renal Insufficiency and Bypass Surgery" Renal Insufficiency and the Heart Symposium, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 9, 2004.

L54) "Causes and Consequences of Contrast-Induced Nephropathy and other Major Adverse Coronary Events" Contrast-Induced Nephropathy: Addressing the Needs of the High Risk Patient. A Satellite Symposium to the American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 9, 2004.

L55) "Chronic Kidney Disease as a Cardiovascular Risk Factor" 2nd Annual Scientific Symposium, AHA of Puerto Rico, San Juan, PR, March 13, 2004

L56) "Modern use of Angiotensin Receptor Blockade in Cardiovascular Disease" 2nd Annual Scientific Symposium, AHA of Puerto Rico, San Juan, PR, March 13, 2004

L57) "Chronic Kidney Disease and Cardiovascular Disease" Satellite Symposium: Impact of Anemia Correction in Cardiovascular Patients, American Society of Hypertension Annual Scientific Session, New York, NY, May 22, 2004.

L58) "Contrast-Induced Nephropathy—Clinical Anomaly or Reality" Satellite Symposium: Selecting Contrast Media - Implications for Patient outcomes, EuroPCR 2004, Paris, France, May 26, 2004.

L59) "Contrast Nephropathy" Intervention 2004. American College of Cardiology Nationwide Symposium, CNN Center, Atlanta, GA, June 2, 2004.

L60) "Technical Issues in Selection of the BNP Assay" Satellite Symposium of the American Association of Clinical Chemistry, Los Angeles, CA, July 28, 2004.

L61) "B-type Natriuretic Peptide in Clinical Practice" New Development in Cardiac Biomarkers for Detection and Management of Cardiovascular Diseases, EBAC Accredited Educational Programme, in conjunction with the European Society of Cardiology 2004 Annual Congress, Munich, Germany, August 30, 2004.

L62) "Hot Topics: Renal Disease and Contrast Nephropathy—Implications for the PCI Patient" Session Moderator, Transcatheter Cardiovascular Therapeutics 2004, September 27, 2004.

L63) "Definition and Pathophysiology of Contrast Nephropathy", "Hot Topics: Renal Disease and Contrast Nephropathy—Implications for the PCI Patient" Transcatheter Cardiovascular Therapeutics 2004, September 27, 2004.

L64) "Use of BNP in Clinical Practice" "Hot Topics: Clinical Utility of Biomarkers" Transcatheter Cardiovascular Therapeutics 2004, September 28, 2004.

L65) "Contrast Media, Renal Insufficiency, and Radiocontrast Nephropathy" Introduction to Cardiac Catheterization and Indications for Percutaneous Interventions, 7th Annual Interventional Cardiology Self Assessment and Review Course, Transcatheter Cardiovascular Therapeutics 2004, September 29, 2004.

L66) "Body Weight—Optimal Targets and How Good are We in Getting There" "Drug Combinations for Cardiovascular Disease" Duke Clinical Research Institute and U.S. Food and Drug Administration Think Tank, Washington, DC, October 8, 2004.

L67) "Does Coronary Calcification Imply Plaque Instability?" Managing Cardiovascular and Calcium/Phosphorus Complications of CKD. Official Luncheon Symposium, Renal Week 2004, American Society of Nephrology, St. Louis, MO, October 20, 2004.

L68) "B-type Natriuretic Peptide in the Diagnosis of Acute Heart Failure," New Advances in the Diagnosis and Management of Acute Decompensated Heart Failure, Satellite Symposium to the AHA Scientific Sessions 2004, New Orleans, LA, November 8, 2004.

L69) "Oportunidades para Aprimoramento no Tratamiento da Insuficiencia Cardiaca," 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insufiencia Cardiaca, I Encontró Multiporfissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portugese) Salvador, Bahía, Brasil, November 25-27, 2004.

L70) "Peptideo Natriuretico Intravenoso-Perspectivas para Emprego na IC Descompensada," 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insufiencia Cardiaca, I Encontro Multiprofissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portugese) Salvador, Bahia, Brasil, November 25-27, 2004.

L71) "Nesiritide (Peptideo Natriuretico Intravenoso) uma Nova Arma no Tratamento da IC Grave e Decompensada," 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insufiencia Cardiaca, I Encontro Multiporfissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portuguese) Salvador, Bahia, Brasil, November 25-27, 2004.

L72) "Conferenca Magna (Keynote Address): The Cardiorenal Intersection: Crossroads to the Future," 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insufiencia Cardiaca, I Encontro Multiporfissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portuguese) Salvador, Bahia, Brasil, November 25-27, 2004.

L73) "Practical Use of BNP in the Diagnosis and Management of Heart Failure" Medical Grand Rounds, Olathe Regional Medical Center, Olathe, KS, December 3, 2004.

L74) "Management of Heart and Renal Failure" The 36th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 18, 2005.

L75) "Contrast-Induced Nephropathy" The 36th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 18, 2005.

L76) "Combined Heart and Kidney Failure" Cardiovascular Conference at Snowmass, Aspen, CO, January 18, 2005.

L77) "Practice Strategies and Protocols to Reduce Renal Complications" PCI: Understanding and Managing In-Hospital Cardiac and Renal Complications, 3rd European Summit, Chantily, France, February 11, 2005.

L78) "HDL Cholesterol: A Powerful New Therapeutic Target" 14th (Conference Chair) Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 14, 2005.

L79) "BNP-ology, is the Enthusiasm Warranted?" (Conference Chair) 14th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 15, 2005.

L80) "Anticoagulation for Atrial Fibrillation: Can Warfarin be Replaced?" (Conference Chair) 14th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 18, 2005.

L81) "New Multimarker Strategies in the Diagnosis of Acute Coronary Syndromes" Satellite Symposium to the 54th Annual American College of Cardiology Scientific Sessions 2005, Orlando, FL, March 7, 2005.

L82) "Effect of Lowering LDL Level on Progression of Vascular Calcification" Reducing the Burden of Cardiovascular Calcification in Chronic Kidney Disease, Satellite Symposium to the Renal Physicians Association Annual Meeting, Washington, DC, March 20, 2005.

L83) "Why Chronic Kidney disease is a CVD risk factor: Practical Implications in the Care of Cardiovascular Patients" Cardiology Grand Rounds, Clinical Science Institute, Galway, Ireland, UK, May 5, 2005.

L84) "Clinical Application of B-type Natriuretic Peptide Levels in the Care of Cardiovascular Patients" EuroLab 2005, Glasgow, Scotland, UK, May 9, 2005.

L85) "Anemia Is a Cardiovascular Risk Factor in Patients With Diabetic Nephropathy" The Kidney is a Key Link between Diabetes and Cardiovascular Disease: Managing Risk; Satellite Symposia to the Annual Scientific Sessions of the American Association of Clinical Endocrinology, Washington, DC, May 18, 2005.

L86) "CIN: Emerging Trends in Identifying and Managing the At-risk Patient" Cardiovascular and Interventional Radiology Society of Europe (CIRSE) 2005, Nice, France, September 13, 2005.

L87) "Recent Advances in Cardiac Markers and their Clinical Role in Cardiovascular Disease: Update of the BNP Consensus Panel Statements and Cost Effectiveness of BNP Testing" Turning Science into Caring Programme, Abbott European Laboratory Symposium, Wiesbaden-Delkenheim, Germany, October 14, 2005.

L88) "Epidemiology and Prevention of Contrast Nephropathy" Transcatheter Therapeutics Annual Scientific Sessions, Washington, DC, October 19, 2005.

L89) "BNP—What Does it All Mean?" Heart Failure 2005: What to Do for the Failing Left Ventricle" AHA Symposium in Conjunction with the 2005 Scientific Sessions, Dallas, TX, November 11, 2005.

L90) "How to Use Cardiac Biomarkers in Heart Failure" 2005 Annual Scientific Sessions of the AHA, Dallas, TX, November 14, 2005, broadcasted nationally as "Best of Sessions 2005 on Wednesday, November 30 from 1:00-2:30PM EST"

L91) "Chronic Kidney Disease as a Cardiovascular Risk State: Practical Management for the Cardiologist" St. Vincent's Hospital, University of British Columbia, Distinguished

Speakers in Cardiovascular Medicine, 2005-2006, Vancouver, BC, Canada, December, 1, 2005.

L92) "Anemia, Chronic Kidney Disease, and Cardiovascular Disease: Diagnosis, Prognosis, and Treatment. Nephrology Grand Rounds, University of British Columbia, St. Vincent's Hospital, Vancouver, BC, Canada, December 2, 2005.

L93) "The Deadly Triangle of Anemia, Kidney and Heart Disease: Implications for Treatment and Management" 37th Annual Cardiovascular Conference at Snowmass, January 20, 2006, Snowmass, CO.

L94) "Anemia in Cardiovascular Patients: Diagnosis, Prognosis, and Therapy." AHA, Prevention VIII Conference: Kidney Disease, Hypertension, and Cardiovascular Disease, January 27, 2006, Orlando, FL.

L95) "Update on Bariatric Surgery" (Conference Chair) 15th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 17, 2006.

L96) "Multimarker Approach to Chest Pain." Satellite Symposium to the Annual Scientific Sessions of the American College of Cardiology, March 11, 2006, Atlanta, GA.

L97) " Preventing Contrast Nephropathy: What Works?" American College of Cardiology Annual Scientific Sessions (ACC.06 and the i2 Summit 2006), March 14, 2006, Atlanta, GA.

L98) "Consensus statements on strategies to reduce the risk of CIN." Satellite Symposium Society for Cardiac Angiography and Intervention 29th Annual Scientific Sessions (Symposium Chair): Consensus Statements on Contrast-Induced Nephropathy (CIN): Report of an International, Multidisciplinary Panel, Chicago, IL, May 11, 2006.

L99) "Contrast-induced nephropathy: identifying and managing the patient at risk." Euro PCR 2006 Satellite Symposium: The Underestimated Impact of Contrast Media on Patient Outcomes in PCI (Symposium Chair), Paris, France, May 27, 2006.

L100) "Debate: Acute Decompensated Heart Failure--Biomarker will suffice" 17th Annual Scientific Sessions of the American Society of Echocardiography, Baltimore, MD, June 6, 2006.

L101) "Heart and Kidney: Clinical Impact of Contrast Media" Update on Cardiovascular Disease 2006, Casa Di Cura Montevergine, Napoli Castel Dell'Ovo, Naples, Italy, June 19, 2006.

L102) "Cardiovascular Disease in CKD: Where Does Calcium Fit In?" Satellite Symposia: Current Strategies for the Management of Hyperphosphatemia in End-Stage Renal Disease.

European Renal Association/European Dialysis and Transplantation Association Annual Scientific Meeting, Glasgow, Scotland, July 17, 2006.

L103) "Applications of BNP in Cardiovascular Disease" Satellite Symposia: New and Evolving Markers for Cardiovascular Disease: Myeloperoxidase (MPO) and BNP. American Association of Clinical Chemistry Annual Meeting, Chicago, IL, July 26, 2006.

L104) "Clinical Applications of B-type Natriuretic Peptide Testing" Clinical Biochemistry Satellite Symposium: The Role of Biochemical Markers in Clinical Cardiology, Sponsored by the Australasian Association of Clinical Biochemists at the 54th Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand, Canberra, Australia, August 4, 2006.

L105) "Update on BNP in the Management of Heart Failure" 54th Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand, Canberra, Australia, August 6, 2006.

L106) "Update on BNP in the Management of Heart Failure" Cardiology Grand Rounds, Royal North Shore Hospital, Sydney, Australia, August 7, 2006.

L107) "Contrast-Induced Nephropathy: Identifying and Managing the Patient at Risk" Advances in Contrast-Enhanced Imaging: Improving Outcomes and Reducing Risks of Iodinated Contrast (Chairman), a CME Satellite Symposium at the Transcatheter Therapeutics 2006 Conference, Washington, DC, October 24, 2006.

L108) "Cardiorenal Syndrome: Etiology, Therapy, and Prognosis" Unresolved Issues in Heart Failure, Cardiovascular Seminars, 2006 Annual Scientific Sessions of the AHA, Chicago, IL, November 14, 2006

L109) "Prevention and Management of CAD in CKD" Coronary Artery Disease in CKD: Updating the Pathophysiology and Management. Official Symposium of the American Society of Nephrology, Sand Diego, CA, November 16, 2006.

L110) "Pharmacologic Prevention of Sudden Death in Dialysis Patients" Sudden Death in Hemodialysis Patients: Towards Prevention. American Society of Nephrology Renal Week 2007, San Diego, CA, November 17, 2006.

L111) "Contrast Nephropathy: Finding Consensus on a Rational Approach" Radiology Grand Rounds, Hôpital Notre-Dame, University of Montreal, Canada, November 23, 2006.

L112) "Contrast Nephropathy: Finding Consensus on a Rational Approach" Radiology Grand Rounds, Hôpital St-Luc, University of Montreal, Canada, November 23, 2006.

L113) "Cardiorenal Syndrome and Anemia" 3rd Annual Heart Failure University (HFU) Cardiovascular Fellows Program, Los Angeles, CA, December 2, 2006.

L114) "Implications of Age-Related Decline in Renal Function" 16th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 12, 2007.

L115) "Using BNP in Your Practice: Pearls and Pitfalls" 16th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 15, 2007.

L116) "Consensus Panel Findings on Contrast Nephropathy" 16th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 16, 2007.

L117) "Measuring BNP in ACS," American College of Cardiology Scientific Sessions Satellite Symposium, "ACS & Biomarkers: From Molecules to Patient Management", New Orleans, LA, March 24, 2007.

L118) "Anemia Correction and CVD Trials" "Ask the Experts" clinicaltrialresults.org, American College of Cardiology Scientific Sessions, New Orleans, LA, March 26, 2007.

L119) "CKD and CVD: Interaction and Risk Factors", Kidney Disease: The Unrecognized Silent Killer, NKF 2007 Scientific Meetings, Orlando, FL, April 11, 2007.

L120) "Contrast-Induced Nephropathy: A Meta-Analyses of the Renal Safety of Iodixanol" Special Lecture for the Radiological Society of the Republic of China, National Yang-Ming University, School of Medicine, Taipei, Taiwan, May 4, 2007.

L121) "Contrast-Induced Nephropathy: A Meta-Analyses of the Renal Safety of Iodixanol" Annual Meeting of Kaohsiung Society of Radiology, Chang Gung Memorial Hospital, Kaohsiung Hsien, Taiwan, May 5, 2007.

L122) "Meta-Analyses of the Renal Safety of Iodixanol", Plenary Session, 15th Annual Scientific Congress of the Hong Kong College of Cardiology, Hong Kong, SAR, May 6, 2007.

L123) "Contrast-Induced Nephropathy: A Meta-Analyses of the Renal Safety of Iodixanol" Cardiology Special Lecture, 12th Department of Cardiology, Beijing AnZhen Hospital, Beijing, Peoples Republic of China, May 7, 2007.

L124) "Prevention of CIN during PCI in Diabetic Patients: Proposal of a Guideline" (Prevencion del Fracaso Renal Inducido por Contraste en Pacientes Diabeticos Sometidos a Intervencionismo Coronario: Propestuesta de un Protocolo Actuacion), Optimizacion del Tratamiento de Revascularizacion Percutanea en Pacientes Diabeticos, TEAM (Terapia Endovascular & Miocardica), Hospital del Mar, Barcelona, Spain, May 11, 2007.

L125) "Acute Kidney Injury from Iodinated Contrast: Findings from an International Panel," Hungarian Society of Cardiology Annual Scientific Meeting (Magyar Kardiologusok Tarsasaga Tudomanyos Kongresszusa) Balatonfured, Hungary, May 12, 2007.

L126) "Which Types and Which Amount of Physical Activities to Achieve and Maintain a Healthy Body Weight?" 4th Metabolic Syndrome, Type II Diabetes, and Atherosclerosis Congress (MSDA), 2007, Lisbon, Portugal, May 19, 2007.

L127) "The Role of BNP in Patients with Shortness of Breath," Laboratory Diagnostic Technologies for Patients with Shortness of Breath, Satellite Symposium to the American Association of Clinical Chemistry Annual Scientific Meeting, San Diego, CA, July 18, 2007.

L128) "Acute Kidney Injury after Contrast: A Serious Problem by Any Name", Hemodynamics, Electrolytes, Acute Kidney Injury: Novel Considerations in Contrast Selection, Transcatheter Cardiovascular Therapeutics 2007 Annual Meeting Satellite Symposium, Washington, DC, October 23, 2007.

L129) "Vascular Calcification: Myth versus Realty: A Cardiologist's Perspective," Changing Paradigms: Evolving Bone and Mineral Metabolism Treatment in CKD, An American Society of Nephrology 2007 Official Symposia, San Francisco, CA, November 3, 2007.

L130) "Contrast-Induced Nephropathy" Cardiology Grand Rounds, Auckland City Hospital, Auckland, New Zealand, November 22, 2007.

L131) "Practical Use of Natriuretic Peptides in Cardiovascular Disease" North Shore Hospital- Waitemata Health, Takapuna, Auckland, New Zealand, November 22, 2007.

L132) "Practical Use of Natriuretic Peptides in Cardiovascular Disease" Waikato Hospital, Hamilton, New Zealand, November 23, 2007.

L133) "Practical Use of Natriuretic Peptides in Cardiovascular Disease" Wakefield Hospital, Adelaide, Australia, November 23, 2007.

L134) "Clinical Utilization of Cardiac Troponin and Natriuretic Peptides in ACS and CHF" Satellite Symposium to Australasian Emergency Meeting (ACEM), Gold Coast, Brisbane, Australia, November 27, 2007.

L135) "Clinical Utilisation of Cardiac Troponin and Natriuretic Peptides in ACS and CHF: Part 1: Congestive Heart Failure, Part 2: Acute Coronary Syndrome, Part 3: Cardio-Renal Syndrome, Kuala Lumpur, Malaysia, November 29, 2007.

L136) "Multimarker Strategies in the Management of Cardiovascular Emergencies," YMCA for Dr. H.F.Ho, Queen Elizabeth Hospital, Hong Kong, SAR, November 30, 2007.

L137) "Practical Management of Cardiovascular Disease in Patients with Kidney Disease" Williamsburg, Virginia for the 34th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 3, 2007.

L138) "New Cardiovascular Drugs" 17th Annual Cardiovascular Conference at Beaver Creek" Avon, CO, February 12, 2008.

L139) "New Insights into Atherosclerosis and Global CVD Risk," 17th Annual Cardiovascular Conference at Beaver Creek" Avon, CO, February 12, 2008.

L140) "Plenary 2 : Mini-Symposia: Acute Kidney Injury (AKI): Pathophysiology: Contrast Nephropathy: Epidemiology and Prognosis" 13th Annual International Conference on Continuous Renal Replacement Therapies, San Diego, CA, February 28, 2008.

L141) "Heart Failure and Cardio-Renal Syndrome 1: Pathophysiology" 13th Annual International Conference on Continuous Renal Replacement Therapies, San Diego, CA, February 29, 2008.

L142) "Hemodynamic Monitoring: Principles and Practice" 13th Annual International Conference on Continuous Renal Replacement Therapies, San Diego, CA, February 29, 2008.

L143) "Cardiovascular Calcification, Potential Strategies in Minimizing Cardiovascular Disease in CKD", Satellite Symposia at the 57th ACC Annual Scientific Sessions, Chicago, IL, March 30, 2008.

L144) "Emergency Evaluation of Chest Pain: Building a Better Mousetrap" Olathe Medical Center Annual Heartbeat Symposium, Olathe, KS, April 4, 2007.

L145) "Interventions and CVD Interactions in Diabetics with Proteinuria" Satellite Symposia (Chairman) Chronic Kidney Disease Interventions: Improving CKD and CVD Outcomes" NKF Clinical Meeting 2008, Dallas, TX, April 5, 2008.

L146) "Shifting Paradigms in PCI: Controversial Issues in High-Risk Patients" International Symposium (Chairman), Barcelona, Spain, April 10, 2008.

L147) "Success in Identifying Heart Failure" Satellite Symposia "Managing CVD: What Every Internist Needs to Know" Annual Scientific Sessions of the American College of Physicians, Washington, DC, May 14, 2008.

L148) "Cardiovascular Calcification in Patients with Chronic Kidney Disease" Satellite Symposia "Cardiovascular Disease in CKD: Strategies for Minimizing Mortality" Annual Scientific Sessions of the American College of Physicians, Washington, DC, May 15, 2008.

L149) "Clinical Trial Designs in Contrast Induced Acute Kidney Injury," Third Annual AKIN Conference on Research Initiatives in AKI, Bethesda, MD, June 10-12, 2008.

L150) "Neutrophil Gelatinase Associated Lipocalin (NGAL)" on Behalf of Inverness Medical, Third Annual AKIN Conference on Research Initiatives in AKI, Bethesda, MD, June 10-12, 2008.

L151) "Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy" Radiological Society of Taiwan, Taipei, Taiwan, July 17, 2008.

L152) "Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy" Radiological Society of Taiwan, Kaushiung, Taiwan, July 18, 2008.

L153) "Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy" Contrast-Induced Nephropathy Symposium, Professor Yalin Han, MD, Chairwoman of Military Cardiology Society of China, Shenyang, China, July 20, 2008.

L154) Cardiology Teaching Rounds, with Professor Runlin Gao, Beijing Fuwai Hospital, Beijing, China, July 21, 2008.

L155) Cardiology Teaching Rounds, with Professor Yujie Zhou, Beijing Anzhen Hospital, Beijing, China, July 21, 2008.

L156) Cardiology Teaching Rounds with Professor Yundai Chen, General Hospital of Military, Peoples Liberation Army, Beijing, China, July 21, 2008.

L157) "Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy" Contrast-Induced Nephropathy Symposium, Contrast-Induced Nephropathy Symposium, Professor Runlin Gao, Chairman of Chinese Cardiology Society, Beijing, China, July 22, 2008.K

L158) "New Insights on Accelerated Vascular Calcification in Patients with Kidney Disease" Plenary Session: Ischemic Heart Disease/Risk Assessment/New Treatment Strategies" International Academy of Cardiology 14th World Congress on Heart Disease, Annual Scientific Sessions, Toronto, Ontario, Canada, July 29, 2008.

L159) "Cardiorenal Syndrome: the Diagnostic Value of Brain Natriuretic Peptide and Neutrophil Gelatinase Associated-Lipocalin in Interventional Cardiology," Cardiovascular Biomarkers which Enhance Clinical Practice in Emergency Medicine and Cardiology: the State of the Art for Markers of Necrosis, Hemodynamic Stress and Cardiorenal Syndrome, Satellite Symposium to the European Society of Cardiology Annual Scientific Sessions, Munich, Germany, September 2, 2008.

L160) "Diagnosis and Management of Diabetes, Hypertension, and Acute Dyspnea," 2008 CVD and CKD Intersection Consensus Conference, Chicago, IL, September 26, 2008.

L161) "Chronic Kidney Disease and Contrast Nephropathy (Contrast-Induced Acute Kidney Injury [CI-AKI]): From Prognostic Scores to the Latest Preventive Strategies" Complex Patients, Complex Lesions, 20th Annual Transcatheter Therapeutics Conference, Washington, DC, October 14, 2008.

L162) "Chronic Kidney Disease: a CHD Risk Equivalent" 2008 Cardiometabolic Health Congress, Harvard Medical School, Boston, MA, October 19, 2008.

L163) "Hyperphosphatemia as a Cardiovascular Risk Factor" Nephrology Conference, The Ottawa Hospital, Ottawa, Ontario, Canada, October 28, 2008.

L164) "Cardiovascular Calcification in Patients with Chronic Kidney Disease" Nephrology Division-Wide Conference, The Ottawa Hospital, Ottawa, Ontario, Canada, October 28, 2008.

L165) "Hyperphosphatemia and CVD Risk," Management of Hyperphosphatemia Across the Continuum of CKD, American Society of Nephrology Satellite Symposium, Philadelphia, PA, November 8, 2008.

L166) "Cardiovascular Calcification" Nephrology Grand Rounds, Humber River Regional Hospital, Toronto, Ontario, Canada, December 9, 2009.

L167) "Cardiovascular Calcification" Nephrology Grand Rounds, St. Joseph's Hospital, Toronto, Ontario, Canada, December 9, 2009.

L168) "Critical Concepts in the Progression of Atherosclerosis" 18th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 9, 2009.

L169) "New Molecular Targets in the Treatment of Atherosclerosis" 18th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 9, 2009.

L170) "Sudden Cardiac Death in Patients with Renal Disease" 18th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 12, 2009.

L171) "Cardiovascular and Renal Implications of Contrast Media" Radiology Grand Rounds, The Kingston Hospital, Queens University School of Medicine, Kingston, Ontario, Canada, March 3, 2009.

L172) "Recent Evidence into the Pathophysiology of Cardiovascular Calcification in Chronic Kidney Disease," NKF Symposium 2009 Spring Clinical Meetings, "Exploring Recent

Evidence Related to Cardiovascular Calcification and Chronic Kidney Disease", Nashville, TN, March 27, 2009.

L173) "Chronic Kidney Disease: Implications For Patients With CAD" Managing the High Risk Coronary Patient, I2 Summit, American College of Cardiology Annual Scientific Sessions, Orlando, FL, March 30, 2009.

L174) "BNP and Cardiovascular Disease" Cardiology Grand Rounds, Hospital PróCardíaco, Rio deJaniero, Brasil, April 14, 2009.

L175) "Acute Cardiac Effects of Marathon Running" Special Guest Lecture, CLINIMEX - Clínica de Medicina do Exercício, Rio deJaniero, Brasil, April 14, 2009.

L176) "Interface entre doenca renal e cardiovascular: o rim mata o coracao ou o coracao mata o rim? Da para evitar esse extermino?" Terapeutica Cardiovascular International, Hospital Espanhol, Salvador, Brasil, April 17, 2009.

L177) "A angiotomografia coronaria deve ser empregada em todo paciente com do toracica de risco baixo-moderado?" Terapeutica Cardiovascular International, Hospital Espanhol, Salvador, Brasil, April 17, 2009.

L178) "Conferencia Internacional: Opportunidades para aperfeicoar o tratamento da insuficiencia cardiaca avancada/descompensada" Terapeutica Cardiovascular International, Hospital Espanhol, Salvador, Brasil, April 17, 2009.

L179) "Invasive Versus Non-invasive Coronary Angiography: Guidelines for Achieving Optimal Outcomes" Annual Scientific Sessions of the Society for Cardiac Angiography and Intervention, Las Vegas, NV, May 7, 2009.

L180) "Cardiorenal Syndrome" Moderator, American Society of Nephrology Annual Scientific Sessions, Renal Week 2009, San Diego, CA, October 29, 2009.

L181) "The Creatinine Changes: Now What?" Cardiorenal Syndromes, Annual Scientific Sessions, AHA, Orlando, FL, November 16, 2009.

L182) "Cardiorenal Syndromes: Strategies for Success" 19th Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 6-11, 2010.

L183) "Cardiomyopathy of Obesity" 19th Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 6-11, 2010.

L184) "Why Does Atherosclerosis Calcify: Clinical Implications" 19th Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 6-11, 2010.

L185) "Prevention Trials in AKI" 15th International Conference on Continuous Renal Replacement Therapies (CRRT: 2010) Scientific Meeting, Del Coronado, CA, February 24, 2010.

L186) "Cardiology Trials" 15th International Conference on Continuous Renal Replacement Therapies (CRRT: 2010) Scientific Meeting, Del Coronado, CA, February 24, 2010.

L187) "Contrast Nephropathy: Prevention and Management" 15th International Conference on Continuous Renal Replacement Therapies (CRRT: 2010) Scientific Meeting, Del Coronado, CA, February 26, 2010.

L188) "Lipoprotein-Associated Phospholipase A2 (Control#: 4599)" Symposium: Do New Markers & Genomics Enhance Risk Prediction? Annual Scientific Sessions of the ACC, Atlanta, GA, March 15, 2010.

L189) "New Insights Into the Role of Heart-Kidney Interactions in the Cardiorenal Syndrome" (Control#: 16660) Symposium: Recognition and Management of the Cardiorenal Syndrome in Advanced Heart Failure, Annual Scientific Sessions of the American College of Cardiology, Atlanta, GA, March 15, 2010.

L190) "B-Type Natriuretic Peptides in Cardiorenal Syndromes" 5th Annual Turning Science into Caring Symposium, Wiesbaden, Germany, March 25, 2010.

L191) "CKD and CVD Interaction in KEEP" KEEP Update: the Common Soil of CKD and CVD, NKF Spring Clinical Meetings, Orlando, FL, April 16, 2010.

L192) "Cardio Renal Intersection, Crossroads to the Future - Novel Coronary Risk Factors" NKF Spring Clinical Meetings, Orlando, FL, April 16, 2010.

L193) "Diagnostic Workup of suspected heart disease in CKD" NKF Spring Clinical Meetings, Orlando, FL, April 17, 2010.

L194) "BNP: Beyond Heart Failure (BNP más allá de la insuficiencia cardiaca)", XIX Chile 2010 Congreso Latinoamericano de Bioquimica Clinica, XVI Congreso Chileno de Quimica Clinica, Biomarcadores en Enfermedades Cario-Renales COLABIOCLI 2010, Santiago del Chile, April 21, 2010.

L195) "Prevention of Cardiorenal Syndromes", 19th International Vicenza Course on Critical Care Nephrology, Vicenza, Italy, June 10, 2010.

L196) "La Pandemia de la Obesidad: Que podemos hacer aquí y ahora" "Importancia de la Evaluación previa y el monitoreo cardiaco en rehabilitación cardiaca" "Ergoespirometria: Diagnostico e implicaciones terapéuticas," Sociedad Columbiana de Cardiologica y Ciruga

Cardiovacular Fundacion Columbiana del Corazon Comite de Prevencion y Rebabilitacion Cardiovascular Dia Mundial del Corazon, Santa Marta, Columbia, September 25, 2010.

L197) "CKD: A CHD Equivalent" 2010 Cardiometabolic Health Congress (CMHC), Boston MA, October 22, 2010.

L198) "Treatment Disparities in Patients with Acute Coronary Syndromes and Kidney Disease" AHA Scientific Sessions 2010, Chicago, IL, November 13, 2010.

L199) "Integration of Advanced Information Technology into Nephrology Practice" Moderator, at the American Society of Nephrology, Denver, CO, November 21, 2010.

L200) "Cardiorenal Syndromes" Special Lecture, Mansoura Nephrology and Urology Center, Mansoura, Egypt, November 29, 2010.

L201) "Neutrophil Gelatinase Associated Lipocalin." Al Mokhtabar Laboratories, Cairo, Egypt, December 1, 2010.

L202) "Cardiorenal Syndromes" ACC Williamsburg Conference, Williamsburg, VA, December 5, 2010.

L203) "Micronutrients and Cardiorenal Disease: Insights into Novel Assessments and Treatment" 13th International Conference on Dialysis, Advances in CKD 2011, Miami, FL, January 26, 2011.

L204) "Managing High Risk Patients in a i2 Spotlight entitled Cardiac Care Team Spotlight: Approaches for CAD Management" American College of Cardiology 60th Annual Scientific Session and i2 Summit 2011, April 2, 2011, in New Orleans, LA.

L205) "Lipid Management in Patients with Renal Insufficiency in a ACC Symposium entitled Lipid Management in Special Populations" American College of Cardiology 60th Annual Scientific Session and i2 Summit 2011, April 2, 2011, in New Orleans, LA.

L206) "KEEP Symposium 2011: KEEP A New Longitudinal Dimension for a New Decade" NKF Spring Clinical Meetings, April 29, 2011, Las Vegas, NV.

L207) "Disparities of Treatment for ACS and Heart Failure in CKD Patients" 20th International Vicenza Course on Hemodialysis and CKD, June 8, 2011, Vicenza, Italy.

L208) "AKI: Can We Prevent It?" 20th International Vicenza Course on Hemodialysis and CKD, June 9, 2011, Vicenza, Italy.

L209) "Measuring Natriuretic Peptides in Acute Coronary Syndromes" American Association of Clinical Chemistry Annual Meeting, Atlanta, GA, July 26, 2011.

L210) "Biomarkers in Stable Angina and Microvascular Dysfunction", Emerging Role of Biomarkers in Cardiorenal Syndrome and Acute Coronary Syndrome: Diagnosis Stratification and Management, Siena Italy, September 2, 2011.

L211) "Cardiorenal Syndrome Definition and Scope: Cardiac Perspective" 28th National Congress of Nephrology, Hypertension, Dialysis, and Transplantation, Antalya, Turkey, October 20, 2011.

L212) "Targeted Hypertension Management for Optimal Cardiorenal Outcomes" 28th National Congress of Nephrology, Hypertension, Dialysis, and Transplantation, Antalya, Turkey, October 22, 2011.

L213) "The KEEP Experience" 3rd International Symposium on Albuminuria – The Prognostic Role of Albuminuria: Impact on Kidney and Cardiovascular Outcomes, Groningen, Netherlands, December 1, 2011.

L214) "Cardiorenal Syndromes" Cardiology Guest Lecture, University of Chicago, Pritzker School of Medicine, Chicago, IL, January 18, 2012.

L215) "Diagnosis of Cardiovascular Disease in CKD" 14th international conference on dialysis, advances in CKD 2012, Palm, Harbor, FL, January 26, 2012

L216) "Acute Kidney Injury Guidelines" KDIGO Clinical Practice Conference: KDIGO Guidelines on Acute Kidney Injury, Glomerulonephritis, and Anemia, Shanghai, China, February 5, 2012

L217) "Galectin-3: A Novel Blood Test for the Evaluation and Management of Heart Failure" Cardiology Grand Rounds, University of Arkansas for Medical Sciences, Little Rock, Arkansas, February 8, 2012

L218) "Contrast-Induced Acute Kidney Injury" 17th Annual CRRT 2012, Acute Kidney Injury Controversies, Challenges, and Solutions, San Diego, CA February 15, 2012

L219) "Recent Trials in the Prevention of Contrast-Induced AKI: Importance of Emerging Biomarkers" 17th Annual CRRT 2012, Acute Kidney Injury Controversies, Challenges, and Solutions, San Diego, CA February 17, 2012

L220) "Role of Galectin-3 in Heart Failure" Joint American Association of Cardiologists of Indian Origin and ACC Dinner Symposium, American College of Cardiology Scientific Sessions 2012, Chicago, IL, March 25, 2012

L221) "Bariatric Surgery: A Cure for Obesity?" American College of Cardiology Scientific Sessions 2012, Joint Symposium of the American Association of Clinical Endocrinologists and

the ACC: Cardiologists as Endocrinologists – Emerging Management of the Diabetic Patient, Chicago, IL, March 26, 2012

L222) "Practical Management of Obesity for the Cardiologist" 48th Annual Robert M. Jeresaty Cardiovascular Symposium, Hartford, CT, May 3, 2012

L223) "Prevention of Cardiovascular Events: Beyond Statins" 48th Annual Robert M. Jeresaty Cardiovascular Symposium, Hartford, CT, May 3, 2012

L224) "Contrast Media and Patient Safety: The Clinical Impact" Swiss Congress of Radiology, Zurich, Switzerland, May 31, 2012

L225) "Importance of Methodological Rigor in CI-AKI Meta-Analyses" 48th Congresso Nazionale Italian Society of Radiology (SIRM), Torino, Italy, June 2, 2012

L226) "Chronic Kidney Disease and Heart Failure" 2012 Cardiometabolic Health Congress (CMHC) Boston, MA, October 12, 2012

L227) "Chronic Kidney Disease and Acute Myocardial Infarction" CKD a Recipe for CVD Disaster, Kidney Week, American Society of Nephrology, San Diego, CA, October 30, 2012

L228) "Epidemiology and Pathophysiology of Coronary Artery Disease in Chronic Kidney Disease" Scientific Sessions 2012, AHA, Los Angeles, CA, November 5, 2012

L229) "The Cardiorenal Syndrome" Acute Dialysis Quality Initiative 11: Cardiorenal Syndromes, Venice, Italy, November 30, 2012

L230) "Cardiorenal Syndromes" Cardiology Grand Rounds, University of Missouri School of Medicine, Columbia, MO, December 20, 2012

L231) "Diagnosis and Management of Coronary Disease in Patients with Kidney Disease" Internal Medicine Grand Rounds, University of Missouri School of Medicine, Columbia, MO, December 20, 2012

L232) "The Hypertension Epidemic: Are We Any Further Ahead?" 22nd Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 9-16, 2013

L233) "Cardiorenal Syndromes: The Cardiac Perspective" Inaugural Cardio Renal Society of America (CRSA), 14th Annual Southwest Nephrology Conference (SWNC), Chandler, AZ, March 2, 2013

L234) "Managing Hyponatremia in Cardiorenal Syndromes" Satellite Symposia to the NKF Spring Clinical Meetings, Orlando, FL, April 3, 2013

L235) "Session Title: Debate: To Screen or Not to Screen for CKD--PRO? NKF Spring Clinical Meetings, Orlando, FL, April 5, 2013

L236) "Galectin-3: A Novel Biomarker for the Assessment and Management of Heart Failure" Heart Failure Conference, University of Pittsburgh Medical Center, Pittsburgh, PA, May 28, 2013

L237) "The Kidney in Heart Failure" 31st International Vicenza Course on Critical Care Nephrology, June 11-14, 2013, Vicenza, Italy

L238) "Contrast-Induced Acute Kidney Injury" 31st International Vicenza Course on Critical Care Nephrology, June 11-14, 2013, Vicenza, Italy

L239) "Novel Biomarkers in the Prognosis and Management of Heart Failure" BUMC Medicine Grand Rounds, August 20, 2013, Dallas, TX

L240) "Cardiorenal Syndromes: New Insights into Combined Heart and Kidney Failure" Cardiology Grand Rounds, University of Virginia Medical Center, August 26, 2013, Charlottesville, VA

L241) "Major Advances in the Treatment of Atherosclerosis: New Options for Patients with Familial Hypercholesterolemia and Those Intolerant to Conventional Lipid Lowering Therapy" Cardiology Update, University of Missouri School of Medicine, September 14, Columbia, MO

L242) "Keynote Address: Recent Advances in the Assessment of Acute Kidney Injury with Neutrophil Gelatinase Associated Lipocalin" 47th Brazilian Congress of Clinical Pathology and Laboratory Medicine, September 23, 2013, Sao Paulo, Brazil.

L243) "Advancements in Cardiometabolic Risk Assessment: Expert Analysis of Recent Evidence and Outcomes" 2013 Cardiometabolic Health Congress, October 2, 2013, Boston, MA.

L244) "Keynote Address: Cardiorenal Syndromes: New Insights to Patients with Combined Heart and Kidney Failure" Fourth Italian Great Network Congress, Focus on Innovation and Translational Research in Emergency Medicine, Sapienza Universita di Roma, October 14-18, 2013, Rome, Italy.

L245) "Practical Experience with Galectin-3" Fourth Italian Great Network Congress, Focus on Innovation and Translational Research in Emergency Medicine, Sapienza Universita di Roma, October 14-18, 2013, Rome, Italy.

L246) "Using Novel Biomarkers in the Assessment and Management of Heart Failure" Bon Secours Cardiovascular Conference, October 25, 2013, Williamsburg, VA

L247) "Detection and Consequences of Iron Deficiency Anemia in CKD Patients" Session Title: The Role of Iron in the Optimization of Anemia Management in CKD, American Society of Nephrology, Kidney Week, November 9, 2013, Atlanta, GA

L248) "Bench to Bedside: What Happens to the Physiologic Systems After an Acute Bout of High Intensity/Volume Exercise?" Session Title: Cardiovascular Seminar entitled Potential Cardiotoxicity of Extreme Endurance Exercise, Annual Scientific Sessions of the AHA, November, 20, 2013, Dallas, TX.

L249) "Atrasentan for the treatment of diabetic nephropathy: how to control the risk of heart failure?" Session Title: "Lessons Learned from First Post FDA Guidance Case Studies of Diabetes CV Outcomes Trials, 10th Global CardioVascular Clinical Trialists (CVCT) Forum, December 7, 2013, Paris, France.

L250) "Reflection: Biomarker-based modeling tools: safer drugs and faster development?" A workshop initiated by the TI-Pharma Escher project for academia, industry, and the European Medicines Agency, January 24, 2014, Amsterdam, the Netherlands.

L251) "Focus on lipids: HDL and Its Associated Lipoproteins in Cardiac and Renal Disease" Changing Paradigms in Acute Kidney Injury: From Mechanisms to Management Sponsored by UAB/UCSD O'Brien Center for AKI Research, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.

L252) "Cardiac and Renal Fibrosis in Chronic Cardiorenal Syndromes" Targeting Recovery from Acute Kidney Injury:, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.

L253) "Statins for AKI: Friend or Foe" Controversies in Critical Care Nephrology:, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.

L254) "Managing Heart Failure and Cardiorenal Syndrome" Workshop, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.

L255) "ST2: A Novel Biomarker in the Assessment and Management of Heart Failure" 2nd Annual Cardio Renal Society of America (CRSA), 15th Annual Southwest Nephrology Conference (SWNC), Ft. McDowell, AZ, March 8, 2014.

L256) "Cardiac and Renal Fibrosis in Chronic Cardiorenal Syndromes" 2nd Annual Cardio Renal Society of America (CRSA), 15th Annual Southwest Nephrology Conference (SWNC), Ft. McDowell, AZ, March 8, 2014.

L257) "New Approaches to the Management of Cardiorenal Syndromes" 2nd Annual Cardio Renal Society of America (CRSA), 15th Annual Southwest Nephrology Conference (SWNC), Ft. McDowell, AZ, March 8, 2014.

L258) "My New Favorite Biomarker: Galectin-3" 2014 UCSD Biomarkers in Clinical Practice Symposium, La Jolla, CA, April 5, 2014.

L259) "Changing Profile of Chronic Hyperkalemia" NKF Spring Clinical Meetings, Las Vegas, NV, April 24, 2014.

L260) "The Next Generation of Screening for Kidney Disease" NKF Spring Clinical Meetings, Las Vegas, NV, April 25, 2014.

L261) "Cardiorenal Syndromes" Cardiology, Diabetes & Nephrology at the Limits, Royal College of Physicians, London, UK, April 26, 2014.

L262) "Acute Cardiorenal Syndromes: New Insights into Combined Heart and Kidney Failure" Actual Problems of Extracorporeal Blood Purification in Intensive Care, Russian Scientific Society of Specialists in Extracorporeal Blood Purification, Bakoulev Scientific Center for Cardiovascular Surgery of the Russian Academy of Medical Sciences, Moscow, Russia, May 22, 2014.

L263) "Fibrosis in the Heart and Kidneys in the Pathogenesis of Chronic Cardiorenal Syndromes" Actual Problems of Extracorporeal Blood Purification in Intensive Care, Russian Scientific Society of Specialists in Extracorporeal Blood Purification, Bakoulev Scientific Center for Cardiovascular Surgery of the Russian Academy of Medical Sciences, Moscow, Russia, May 23, 2014.

L264) "Hyperkalemia: Old Foe with New Faces" 51st European Renal Association – European Dialysis and Transplantation Association Congress, Amsterdam, the Netherlands, June 2, 2014.

L265) "Contrast Induced Complications in the Cath Lab" Transcatheter Cardiovascular Therapeutics (TCT) Russia, Moscow, Russia, June 16, 2014.

L266) "The RAASi Debate: Should RAAS Continue with a Declining GFR?: Will the Path be Clearer" Co-Chair, European Society of Cardiology, Barcelona, Spain, August 31, 2014.

L267) "Novel Markers of Acute and Chronic Kidney Injury," Where Inflammation Meets Lipids: Broad Based Strategies for Risk Reduction, Cleveland Heart Labs, Cleveland, OH, September 12, 2014.

L268) "Advances in the Understanding of Acute and Chronic Cardiorenal Syndromes: Pathophysiological Crosstalk of Multiple Metabolic and Neurohormonal Systems" 41st Williamsburg Cardiovascular Conference, Williamsburg, VA, December 7, 2014.

L269) "CHADS, CHADS-VASc, HAS-BLED, What Does it Mean and How Do We Use It? Atrial Fibrillation Session, Dallas-Leipzig Valve 2104, Dallas, TX, December 11, 2014.

L270) "Soup-to-Nuts Renal Failure: Caring for the Patient with Kidney Injury" Society of Critical Care Medicine, Phoenix, AZ, January 19, 2015.

L271) "RAASi Optimization in Heart Failure" 2nd Annual Cardiorenal Society of America Meeting, Phoenix, AS, February 28, 2015.

L272) "Cardiac Surgery Associated Acute Kidney Injury" Association of Physician Assistants in Cardiac Surgery, Las Vegas, NV, March 3, 2015.

L273) "The Potassium Challenge in CKD: Managing Acute and Chronic Hyperkalemia: Novel Polymer-Based Potassium Binders: Clinical Evidence" NKF Spring Clinical Meetings, March 27, 2015.

L274) "KEEP Healthy: Insights into CKD Care" NKF Spring Clinical Meetings, March 28, 2015.

L275) "The Heart of the Matter" NKF Spring Clinical Meetings, March 28, 2015.

L276) "Literature Review: CVD" NKF Spring Clinical Meetings, March 28, 2015.

L277) "Biomarkers of Kidney and Heart Injury in Cardiorenal Syndrome" Cardionephrology 2015, Rome, Italy, April 16, 2015.

L278) "AKI after Acute Myocardial Infarction: Contrast, Organ Crosstalk and Complications" 33rd Vicenza Course on Critical Care Nephrology in Vicenza, Italy, June 9-12, 2015.

L279) "A New Mechanism of Action for Addressing Hyperkalemia: New Data on Non-Polymer Hyperkalemia Therapies" 33rd Vicenza Course on Critical Care Nephrology in Vicenza, Italy, June 9-12, 2015.

L280) "Lp-PLA2 as a marker of Vascular Inflammation and CHD Risk Assessment" Symposium: Advances in Laboratory Testing for Coronary Heart Disease; The New PLAC Test for Lp-PLA2 Activity, American Association of Clinical Chemistry Annual Meeting, Atlanta, GA, June 29, 2015.

L281) "Galectin-3 in the Prognosis and Management of Heart Failure" American Association of Clinical Chemistry Annual Meeting, Atlanta, GA, June 29, 2015.

L282) "Cardio-Renal Syndrome and Clinical Implications" AKI from Pathophysiology to Clinical Implications, Global Research on Acute Conditions Team (GREAT) Annual Meeting, Rome, Italy, September 5, 2015.

L283) "Lp-PLA2 and Testing for Primary Prevention Risk Assessment" 2015 Cardiometabolic Health Congress, Harvard Medical School, Boston, MA, October 22, 2015.

L284) "Heart and Kidney: a Dangerous Liaison" Comorbidities in Heart Failure: From Guidelines to Clinical Practice, 775 Anniversary University of Sienna, Sienna, Italy, October 29, 2015.

L285) "Role of BNP, Pro-BNP, and Elevated Left Ventricular Mass in Cardiorenal Syndrome" American Society of Nephrology Kidney Week, San Diego, CA, November 6, 2015.

L286) "How to Use Urine Thromboxane B2 to Select and Monitor Aspirin Therapy" Moderator, Scientific Sessions 2015, AHA, Orlando, FL, November 10, 2015.

L287) "Putting it All Together: How to Use Urine 11-Dehydrothromboxane B2 In Clinical Practice" Scientific Sessions 2015, AHA, Orlando, FL, November 10, 2015.

L288) "Neurogenic Orthostatic Hypotension" Moderator, Scientific Sessions 2015, AHA, Orlando, FL, November 10, 2015.

L289) "Cardiac Cachexia" Managing Disease Related Lean Body Mass Loss Through Clinical and Nutritional Interventions, The Sackler Institute for Nutrition Science The New York Academy of Sciences, New York, NY, December 4, 2015.

L290) "The Devastating Consequences of Systemic Hypertension and What To Do About It?" 42st Williamsburg Cardiovascular Conference, Williamsburg, VA, December 6-8, 2015.

L291) "The Impact and Management of Malnutrition in Patients with Heart Failure" Heart Failure University 2015, Conference Co-Chair, Los Angeles, CA, December 11-13, 2015.

L292) "Acute and Chronic Cardiovascular Effects of Hyperkalemia: New Insights Into Prevention and Clinical Management" Heart Failure University 2015, Conference Co-Chair, Los Angeles, CA, December 11-13, 2015.

L293) "Lipoic Acid in the Prevention of Acute Kidney Injury" 21st International Conference on Continuous Renal Replacement Therapies CRRT 2016, San Diego, CA, February 16-18, 2016.

L294) "Novel Approaches for Recognition and Management of Life Threatening Complications of AKI and CKD" 21st International Conference on Continuous Renal Replacement Therapies CRRT 2016, San Diego, CA, February 16-18, 2016.

L295) "Making Iodinated Contrast Less Nephrotoxic with Cyclodextrin" 21st International Conference on Continuous Renal Replacement Therapies CRRT 2016, San Diego, CA, February 16-18, 2016.

L296) "Cardiorenal Syndrome" 4th Annual Cardio-Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ, March 13, 2016.

L297) "Cardiorenal Syndromes Identification: Prevention and Management of CI-AKI" China Interventional Therapeutics (CIT), Beijing, Shanghai Zhong Shan Hospital, Shanghai, The 2nd Affiliated Hospital of Zhejiang University, Hangzhou, Xi Jing Hospital, Xi'an, Nanjing 1st Hospital, Nanjing, Peoples Republic of China, March 14-21, 2016.

L298) "Cardiorenal Syndromes" Keynote Address, Inaugural Cardio-Renal Connections Meeting, San Antonio, TX , April 16, 2016.

L299) "Galectin-3 in the Prognosis and Management of Heart Failure" American Association of Clinical Chemistry Annual Scientific Meeting, Philadelphia, PA, August 1, 2016.

L300) Hemodialysis University, "Is It Heart Failure or Fluid Overload?", Chicago, IL, September 10, 2016.

L301) "Novel Agents for the Treatment of Hyperkalemia" Heart Failure Society of America Annual Scientific Meeting, Orlando, FL, September 18, 2016.

L302) Symposium "Hyperkalemia in the Emergency Department: Updates on the Current Management of a Complex Condition." "Novel Agents for the Prevention and Treatment of Hyperkalemia" American College of Emergency Physicians Scientific Assembly, Las Vegas, NV, October 14, 2016

L303) Moderator "CVD in Patients with CKD: Update from the CRIC Study" Annual Scientific Sessions of the AHA, New Orleans, LA, November 13, 2016

L304) Program Chairman "A Night at the Museum: Inaugural Symposium of the Cardiorenal Society of America Transcending the Dinosaurs: Guiding AKI Prevention using next-gen biomarkers: Real World Experiences from modern practices" satellite Symposium at American Society of Nephrology Kidney Week, Field Museum, Chicago, IL, November 18, 2016

L305) "Pathobiologic Systems Involved in Cardiorenal Disease" 43rd Williamsburg Cardiovascular Conference, Williamsburg, VA, December 3-5, 2016

L306) "Cardiac Cachexia" Heart Failure University, MedReviews LLC, Los Angeles, CA, December 10, 2016

L307) "Is There a Role for Bariatric Surgery in Heart Failure Patients with Obesity?" Scientific Sessions 2017, American College of Cardiology , Washington, DC, March 18, 2017

L308) "Vascular and Cardiac Hypertrophy in Fabry Disease" 5th Annual Fabry Nephropathy Update, Mexico City, Mexico, April 26, 2017

L309) "Introduction to Cardiorenal Medicine" Cardiorenal University, Anaheim, CA, May 18, 2017

L310) "Sudden Death in End-Stage Renal Disease" Cardiorenal University, Anaheim, CA, May 18, 2017

L311) "Cardiorenal Syndromes and Heart Failure" Conference Chair, Disease Global Outcomes (KDIGO) Controversies Conference on Heart Failure in Chronic Kidney Disease, Athens, Greece, May 25-28, 2017

L312) "Vadadustat Does Not Prolong Corrected QT Interval In A Thorough QTC Study In Healthy Subjects" 54th ERA-EDTA Congress, Madrid, Spain, June 3-6, 2017

L313) "Cardiorenal Syndromes" 1st Annual Heart iN Diabetes: Where the Heart, Kidney, and Diabetes Meet in Clinical Practice, Philadelphia, PA, July 14-16, 2017

L314) "Cardiovascular Disease in Patients with Chronic Kidney Disease: A Serious Link" TOP 2017--Target Organ Protection Conference, Bangalore, India, August 11, 2017

L315) "Statin Therapy to Prevent Onset and Progression of Vascular Disease" TOP 2017--Target Organ Protection Conference, Bangalore, India, August 11, 2017

L316) "Keynote Address: Cardiorenal Society of America" 5th Annual Scientific Meeting of the Cardiorenal Society of America, Phoenix, AZ, October 6, 2017

L317) "Cardiovascular Benefits of Home Hemodialysis" Addressing Unmet Needs in Dialysis: Cardiovascular Care and Volume Control Symposium, Kidney Week 2017 American Society of Nephrology, New Orleans, LA, November 4, 2017

L318) "CIEDs in ESRD Patients: What Are the Long-Term Data?" Kidney Week 2017 American Society of Nephrology, New Orleans, LA, November 4, 2017

L319) "Cardiovascular Seminar Cardiorenal Syndrome: Who hurts who?" AHA Scientific Sessions 2017, Anaheim, CA, November 14, 2017

L320) "Cardiac and Renal Fibrosis in CRS" AHA Scientific Sessions 2017, Anaheim, CA, November 14, 2017

L321) Chair, Inaugural Cardiometabolic University and Nutrition Academy "The Skinny on Weight Loss: Practical Considerations for the Cardiovascular Specialist" MedReviews, Westlake, TX, December 1-3, 2017

L322) "Clinical Laboratory Advancements in Cardiometabolic Disease: Screening, Diagnosis, Prognosis, and Management" 44th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 4, 2017

L323) "The Skinny on Weight Loss: Practical Approaches for the Cardiovascular Specialist" Cardiometabolic University 2017, Conference Chair, Dallas, TX , December 1-3, 2017

L324) "Diagnosis, Evaluation, and Role of Biomarkers in Heart Failure" Heart Failure University 2017, Conference Co-Chair, Los Angeles, CA, December 10-12, 2017

L325) "Biomarkers of Kidney Dysfunction and Cardiorenal Syndrome" University of California at San Diego 14th Annual Biomarkers in Heart Failure and Acute Coronary Syndromes: Diagnosis, Treatment and Devices, San Diego, CA, March 2, 2018

L326) "What do I do to Prevent Contrast Induced Renal Injury" 23rd International Conference on Continuous Renal Replacement Therapies CRRT 2018, San Diego, CA, March 8, 2018

L327) "AKI in the patient with Cancer" 23rd International Conference on Continuous Renal Replacement Therapies CRRT 2018, San Diego, CA, March 8, 2018.

L328) "CKD-Related Anemia and Cardiac Complications" NKF Spring Clinical Meetings, Austin, TX April 14, 2018

L329) "Principles of Distributive Shock" Cardiorenal Society of America National Grand Rounds Series, Boston, MA, April 30, 2018

L330) "Biomarkers with More Muscle: Moving Beyond Serum Creatinine to Define Cardiorenal Syndrome in HF" Heart Failure Society of American Annual Scientific Sessions, Nashville, TN, September 15, 2018

L331) "Heart Failure in Cardiorenal Syndrome: Updates on Biomarkers" Cardiorenal Society of America Annual Scientific Meeting, Phoenix, AZ, October 6, 2018

L332) "Novel Approaches in Lowering LDL-C" Cardiorenal Society of America Annual Scientific Meeting, Phoenix, AZ, October 6, 2018

L333) "What Do We Know About Cardiorenal Physiology? An Overview" American Society of Nephrology Kidney Week, San Diego, CA, October 26, 2018

L334) "Prevention of Heart Failure: The Next Frontier" Cardiometabolic Health Conference, Boston, MA, October 27, 2018

L335) "AKI and Heart Failure: How to Manage Compared to the General Population" Cardiometabolic Health Conference, Boston, MA, October 27, 2018

L336) "SGLT-2 Inhibitors and Cardio-renal Outcomes: Mechanistic Role and Rationale for Treatment of Heart Failure" American Heart Association Annual Scientific Sessions, Chicago, IL, November 10, 2018

L337) "Obesity and Heart Disease" 44th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 4, 2018

L338) "Current Concepts in Hypertension Management" University of Texas Health Science Center, Tyler, TX, January 15, 2019

L339) "Managing the Heart Failure Patient with Worsening Renal Function (WRF)" 24th International Conference on Continuous Renal Replacement Therapies CRRT 2019, San Diego, CA, February 28, 2019

L340) "Cardiorenal Syndrome: What Have We Learned?" 24th International Conference on Continuous Renal Replacement Therapies CRRT 2019, San Diego, CA, February 28, 2019

L341) " Debate: Biomarker Guided Heart Failure Therapy: Con: Neuropeptides; ST2" 15th Annual USCD Biomarkers in Heart Failure and Acute Coronary Syndromes, Diagnosis, Treatment & Devices, La Jolla, CA March 1, 2019

L342) "Cardiorenal Syndromes" Cardionephrology Congress, Rome, March 12 to 14, 2019

L343) "Iron and Heart Failure" Cardiometabolic Health Congress West meeting in Phoenix, AZ on Saturday, May 4, 2019

L344) "Up to Date Management of Arrhythmias in Dialysis Patients" National Kidney Foundation Spring Clinical Meetings, May 11, 2019

L345) "Lipids in Chronic Kidney Disease" National Kidney Foundation Spring Clinical Meetings, May 11, 2019

L346) "Cardiorenal Syndromes" Helen Dunham Cardio-Renal Lecture and Cardiovascular Grand Rounds, Brigham and Women's Hospital, Boston, MA, May 23, 2019

L347) "Chronic Kidney Disease as a Cardiovascular Risk State" Helen Dunham Cardio-Renal Lecture and Cardiovascular Grand Rounds, Brigham and Women's Hospital, Boston, MA, May 23, 2019

L348) "Biomarkers and Assessment of Cardiac Function In Fabry Cardiomyopathy" 6th Update on Fabry Disease: Biomarkers, Progression and Treatment Opportunities, Prague, Czech Republic, May 26-28, 2019

L349) "Contrast-Induced Acute Kidney Injury" 37th Vicenza Course on AKI &CRRT, Vicenza, Italy, May, 28-30 2019

L350) "Cardiac Biomarkers in AKI" 37th Vicenza Course on AKI &CRRT, Vicenza, Italy, May, 28-30 2019

L351) "Risk Mitigation in the Cardiac Catheterization Laboratory" 37th Vicenza Course on AKI &CRRT, Vicenza, Italy, May, 28-30 2019

L352) "Pathophysiology and Current Concepts in Classification" Clinical Practice Clinical Science Track: Treatment of Cardiorenal Syndrome, American Heart Association Hypertension Scientific Sessions, New Orleans, LA, Sept 8, 2019

L353) "Cardiovascular Genetics" 44th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 9, 2019

L354) "Cardiorenal Syndromes" 17th World Congress on Insulin Resistance, Diabetes & Cardiovascular Disease (WCIRDC), Los Angeles, CA, December 4-7, 2019

L355) "Cardiorenal Syndromes" Internal Medicine Grand Rounds, Eastern Virginia College of Medicine, Norfolk, VA, February 19, 2020

L356) "Keynote Address: Prevention of Heart and Kidney Disease" Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 6, 2020

L357) "Cardioprotective Effects of Antidiabetic Medications: Focus on Sodium-Glucose Transporter-2 Antagonists" Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 7, 2020

L358) "Fabry Disease: A Unique Cardiorenal Model" Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 7, 2020

L359) "Biomarkers in Heart and Kidney Disease: Practical Applications" Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 7, 2020

L360) "Expert Briefing from ADA 2020 Select Sessions: Update on Heart Failure for the Diabetologist & Cardiorenal–Metabolic Axis in Diabetes" American Diabetes Association, June 14, 2020

L361) "CKD, CHD and Hyperkalaemia: Clinical Outcomes, Morbidity and Mortality" American College of Cardiology - American Society of Nephrology Masterclass September 11, 2020

L362) "RAASi Enabling in Cardiology Practice - Traditional vs New Potassium Binders; Potassium Binders for Treatment of Hyperkalaemia in HF" American College of Cardiology - American Society of Nephrology Masterclass September 11, 2020

L363) "Optimizing Transitions from Hospital to Home: Best Practices for Reducing Readmissions in Heart Failure" Hospital Management Summit, October 3, 2020.

L364) "Assessment and Management of Hyperkalemia in the Hospital Setting: Optimizing Patient Outcomes" Hospital Management Summit, October 3, 2020.

L365) "Navigating the Challenges of Cardio-Renal Syndrome" 7th Annual Kansas Cardiovascular Symposium, October 10, 2020

L366) "Management Considerations for Heart Failure in CKD" American Society of Nephrology Kidney Week 2020, October 24, 2020

L367) "Pathophysiologic Basis and Rationale for Early Ambulatory Treatment of SARS-CoV-2 (COVID-19), SciInov, November 2, 2020

L368) "CV and Renal Benefits with new anti-diabetes medications: Potential Mechanisms" CReDO Conferences Middle East North Africa (MENA) 2020, November 6, 2020

L369) "Consequences of Witholding GDMT for Heart Failure in CKD: One Step Forward, Two Steps Back" AHA 2020 November 16, 2020

L370) "Early Ambulatory Treatment for SARS-CoV-2 (COVID-19)" Early Outpatient Treatment: An Essential Part of a COVID-19 Solution. US. Senate Committee on Homeland Security and Governmental Affairs, Washington DC November 19, 2020

L371) "Pathophysiological Basis & Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection" 18th Annual World Congress Insulin Resistance Diabetes & Cardiovascular Disease, December 3, 2020

INTERNAL COMMITTEE POSITIONS

1) Member, Henry Ford Medical Group Hypertension Control Committee, 1998.

2) Ranking Member and Presenter, HFHS Institutional Review Board, 1998-2000.

3) Member, HFHS Teaching and Education Committee, Co-Chair of the Research Subcommittee, 1999-2000

4) Member, HFHS Graduate Medical Education Committee, 1999-2000.

5) Member, HFHS, Internal Medicine Residency Selection Committee, 1998-2000.

6) Chair, HFHS, Cardiovascular Diseases Fellowship Program Selection Committee, 1999-2000.

7) Co-Chair, HFHS, Information Technology and Medical Records Committee, 1999-2000.

8) Member, HFHS Department of Internal Medicine, Research Committee, 1999-2000.

9) Member, UMKC Adult Health Sciences Institutional Review Board, 2001-2002

10) Member, UMKC, Cardiovascular Diseases Fellowship Program Selection Committee, 2000-2002

11) Member, Truman Medical Center (TMC) Information Technology Steering Committee, 2001-2002.

12) Member, WBH Diabetes Research Center Steering Committee, 2002-2003

13) Chairperson, WBH Staff Privileges Appeals Committee, March 31, 2004

14) Chairperson, WBH Search Committee for Medical Director of Transplantation Medicine, 2005-2006

15) WBH Research Institute Board of Governors, board member, 2007-2010

16) Oakland University William Beaumont School of Medicine, Medical Student Committee (founding) for development of Liaison Committee on Medical Education (LCME) application, 2007-2010

17) St. John Providence Health System Graduate Medical Education Steering Committee (Chair), 2010 to 2013

18) St. John Providence Health System Research Leaders Committee, Chair, 2010 to 2012; Co-Chair 2012 to 2013

19) Ascension Michigan Research Affinity Group, Chair, 2010 to 2012; Co-Chair 2012 to 2013

20) St. John Providence Health System Executive Committee, 2011 to 2013

21) St. John Providence Health System Guidelines Committee, 2012 to 2013

22) St. John Providence Health System Presidents Council, 2012 to 2013

23) St. John Providence Health System Electronic Medical Record Meaningful Use Steering Committee, 2013

24) BUMC Graduate Medical Education Committee, 2014 to present

25) BUMC Internal Medicine Residency Program Clinical Competency Committee, 2014 to present

26) BUMC Clinical Cardiology Fellowship Program Clinical Competency Committee, 2014 to present

27) BUMC Founding Member, Department of Molecular Pathology and Medicine, 2016 to present

28) BUMC Precision Medicine Executive Committee, 2016 to present

29) BUMC COVID-19 Therapeutic Task Force 2020

EXTERNAL COMMITTEE POSITIONS

1) Member, AHA National Women's Heart Disease and Stroke Campaign, Healthcare Provider Sub-Group, Dallas, TX, 1998-1999

2) Member, AHA, Chronic Coronary Disease in the Elderly National Database Planning Committee, Dallas, TX, 1998-2000

3) Chair, Michigan Chapter of the American College of Cardiology, Annual Mini-Board Review, 1999-2000

4) Member, Michigan Chapter of the American College of Cardiology, Annual Meeting Planning Committee, 1999-2000

5) Member, National Kidney Disease Outcomes Quality Initiative (K/DOQI) Clinical Practice Guidelines Committee on Chronic Kidney Disease, Andrew S. Levey, MD, Chair, 2001-2002

6) Member, K/DOQI Learning System (KLS)™ Advisory Board, NKF, New York, NY, 2003 to 2010

7) Member, International EECP Patient Registry Working Group, 2003-2008.

8) Counselor at large, Michigan Chapter of the American College of Cardiology, 2004-2006

9) Member, Planning Committee, AHA, Prevention VIII Conference: Kidney Disease, Hypertension, and Cardiovascular Disease, January 26-28, 2006, Orlando, FL

10) Chair, Contrast-Induced Nephropathy (CIN) Working Group Consensus Panel, (international, multispecialty, consensus panel with published findings) 2004-2006. Published in *Am J Cardiol* 2006 Vol 98(6)

11) Workgroup Member, Kidney Disease Improving Global Outcomes (KDIGO), United States Representative, Amsterdam, Netherlands, 2004, 2006

12) Member, Kidney Disease Improving Global Outcomes (KDIGO) Group for the development of Clinical Practice Guidelines for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease Related Mineral and Bone Disorders (CKD-MBD), Paris, France, 2007-2008

13) Board of Directors Member, Kidney Disease Improving Global Outcomes (KDIGO), United States Representative, Brussels, Belgium, 2007-2010

14) Workgroup Member, The Sixth International Acute Dialysis Quality Initiative (ADQI) Consensus Conference VI: Acute Kidney Injury in Cardiac Surgery, Vicenza, Italy May 27 – 28, 2007

15) Workgroup Leader, Prevention: The Seventh International Acute Dialysis Quality Initiative (ADQI) Consensus Conference VII: Cardiorenal Syndrome, Venice, Italy, September 4-5, 2008, with publication n *Nephrology, Dialysis, and Transplantation*, 2010.

16) Chairman, Natriuretic Peptide Testing in Acute Coronary Syndromes Consensus Panel, with published findings in *Reviews in Cardiovascular Medicine* 2010, Dallas, TX, March 2, 2010

17) Scientific Advisory Board, NKF, New York, NY, 2010 to present

18) Scientific Advisory Board, Cardiorenal Society of America, Phoenix, AZ, 2012 to present

19) Workgroup Member, "Cardiovascular Disease in CKD: What is it and what can we do about it?" Kidney Disease Improving Global Outcomes (KDIGO), October 29-31, 2010, London, England.

20) Chairman, "Cardio-Renal Syndromes II: from pathophysiology to therapy" Eleventh Consensus Conference Cardio-Renal Syndromes II November 30 – December 2, 2012, Venice, Italy.

21) Conference Co-Chair: "Kidney Disease Global Outcomes (KDIGO) Controversies Conference on Heart Failure in Chronic Kidney Disease", Athens, Greece, May 25-28, 2017

22) Chairman, "Cardiometabolic University", Dallas, TX, December 3-4, 2017

23) Chair, American Heart Association Council on the Kidney in Cardiovascular Disease and Council on Clinical Cardiology. Cardiorenal Syndrome: Classification, Pathophysiology, Diagnosis, and Treatment Strategies: A Scientific Statement From the American Heart Association, 2019

24) Committee Member, American College of Cardiology, Navigating Treatment Decisions for Patients with ASCVD and Multiple Comorbidities Committee, 2019-2020

25) National and International Advisor/Reviewer/Presenter/Contributor for 4D Molecular Therapies, ABC News, Abbott Laboratories, AbbVie, Advanced Health Media, Aegerion, Affymax, Akceia, Akebia, Alere North America, AMAG, Amersham, Amgen, Amylin, AntiSeptiscope, Aralez, Ardian, Adelyx, Arra Hitech, Astellas, AstraZeneca, Astute Medical, Atherotech, Axio, BG Medicine, Avenue Therapeutics, Aventyn, Back Bay Lifescience Advisors, Bayer, Biocritique, Bioexpertise, Biomarin, Bionest Partners, Bioporto, Biosite, Biostar, BioZ, Boehringer Ingelheim, Braintree Laboratories, Broeker, Bristol Myer Squibb, Cardiokine, Cardiorentis, Chapman and Priest, Charles River Associates, Chelsea Therapeutics, Chiesi USA, ClearView Healthcare Partners, Clinipace, Complexa, Connected Research and Consulting, CorMedix, Cornerstone Therapeutics, Corvidia, Covance, Critical Diagnostics, Cromsource, Crossover Technologies, Chrysalis BioTherapeutics, Cytopheryx, Cytel, DaVita, Daws, DeMatteo Monness, Diadexus, Daiichi Sankyo, Decision Resources, ECG Healthcare, Edwards Life Sciences, Elsevier, Espirion, F. Hoffmann-La Roche Ltd, Fast Biomedical, Fish and Richardson, LLC, Fisher Scientific, FlowMedica Inc, Frictionless Digital, Fresenius Medical Care, General Electric, Genzyme, Gerson Lehrman, Gilead, GVI Clinical Development Solutions, Health Law Partners, Healthspan DX, HealthSTAR Communications, Hershey, Hikari, Hogan Lovells, Hudson Global, ICON, Huff, Powell, and Bailey, LLC, IMC Press, Imidex, Impact Education, Instrumentation Laboratories, Intercept Pharmaceuticals, Intrinsic Life Sciences, Ischemix Technologies, Janssen, Jannsen, Johnson and Johnson, Jordan, KAI Research, Keryx, Ketchum, Inc, Knowledge Point 360, Kowa, Eli Lilly, LabCorp, Lewis Brisbois, Liberty Dialysis, Ligand, Lipocine, Litchfield Cavo, Luitpold Pharmaceuticals,

Lundbeck, Maxaccess Managed Markets, MannKind, MEDACorp, MedEd Group, Medevera, Medical Exchange International, Medical Package, Medicines Company, Medicure Pharma, Inc., MedReviews, Medscape, Medtronic, Merck, Meridian 361 International Law Group, Meso Scale Diagnostics, Miller Tanner Associates, Mitsubishi, Nanomix, Nanosphere, Nabi Biopharmaceuticals, Navigant, NephroGenix, Neumedicines, Noorik GmbH, Norman, Hanson, and Detroy, LLC, Novartis, NovoNordisk, NxStage, Ortho Clinical Diagnostics, Osprey, Otsuka, Overcome, P-value Communications, Parexel, Pharmapprove, Pfizer, Phoenix Holdings, Physicians World, PLC Medical, Praetego, PriMed, Progenabiome, Quidel Corporation, Qualidigm, Quintiles, Reata, Reliant Pharmaceuticals, Renew Research, Relypsa, Repros Therapeutics, Roche Diagnostics, Rock Creek, Saferox, Saghmos Therapeutics, Salix, Sanfit, Sankyo, Sanofi, Sarepta Therapeutics, Scarritt Group, Sentinel Investment, Sloan Law Firm, Sphingotec, Spectracell, St. Jude Medical, Strataca Systems, Statprobe, Sunshine Heart, Synageva, Takeda, Tasly, TheHill, Thrasos, TrialSiteNews, Trinity, Triptych Health Partners, US Medical Management, Vasomedical, Verrow, Vindico, Visiting Physicians Association, Vitalmetrix, Vivus, Watermark, WebMD, ZS Pharma, Inc.

FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

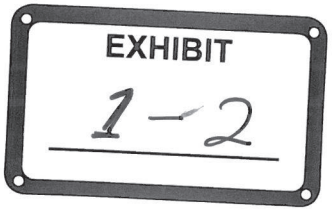
WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.



WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?
Side effects that have been reported with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Moderna COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in **v-safe. V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?
It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?
Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?
No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

HOW CAN I LEARN MORE?

- Ask the vaccination provider
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Contact your state or local public health department

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

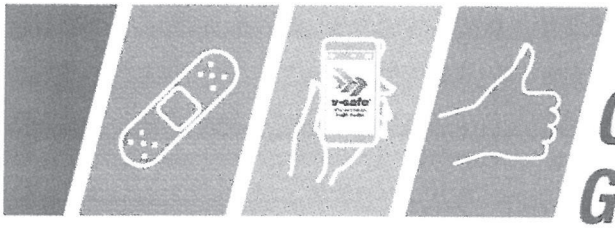
The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Patent(s): www.modernatx.com/patents
Revised: 12/2020

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date 12/2020



Get vaccinated. Get your smartphone. Get started with v-safe.

What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through ***v-safe***, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And ***v-safe*** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's ***v-safe*** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in ***v-safe*** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from ***v-safe*** around 2pm local time. To opt out, simply text "STOP" when ***v-safe*** sends you a text message. You can also start ***v-safe*** again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, ***v-safe*** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions ***v-safe*** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, ***v-safe*** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in ***v-safe*** is protected so that it stays confidential and private.*

*To the extent ***v-safe*** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

12/01/20

v-safe℠
after vaccination health checker

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

Sign up with your smartphone's browser at
vsafe.cdc.gov

OR

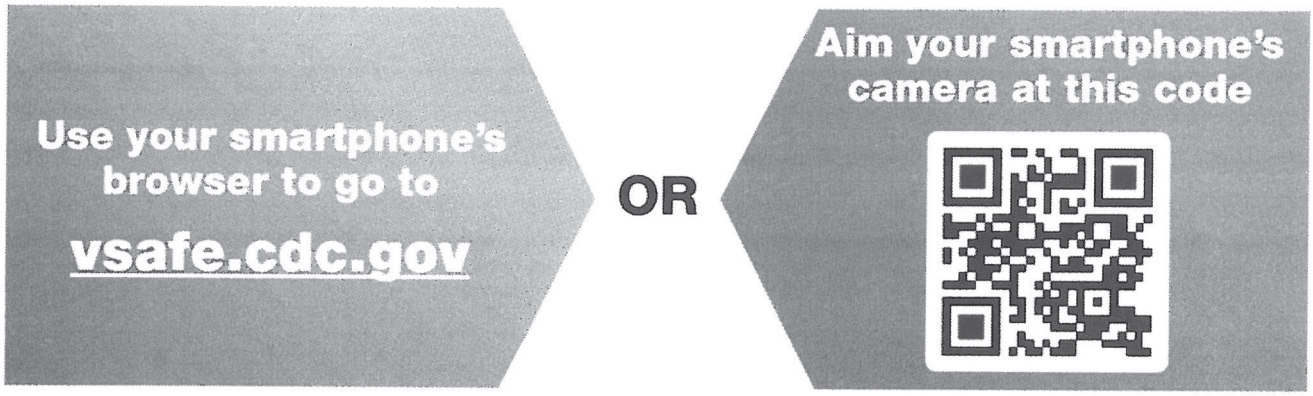
Aim your smartphone's camera at this code

How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

Register

1. Go to the ***v-safe*** website using one of the two options below:



2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in ***v-safe*** and click **Verify**.
5. At the top of the screen, click **Enter your COVID-19 vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2pm local time, ***v-safe*** will start your initial health check-in around 2pm that day. If you register after 2pm, ***v-safe*** will start your initial health check-in immediately after you register—just follow the instructions.

   You will receive a reminder text message from ***v-safe*** when it's time for the next check-in—around 2pm local time. Just click the link in the text message to start the check-in.

Complete a v-safe health check-in

1. When you receive a ***v-safe*** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

Troubleshooting

How can I come back and finish a check-in later if I'm interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

How do I update my vaccine information after my second COVID-19 vaccine dose?

- ***V-safe*** will automatically ask you to update your second dose information. Just follow the instructions.

Need help with *v-safe*?
Call 800-CDC-INFO (800-232-4636)
TTY 888-232-6348
Open 24 hours, 7 days a week
Visit www.cdc.gov/vsafe

vaccines

MDPI

Review

SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Host Cells: Implications for Possible Consequences of COVID-19 Vaccines

Yuichiro J. Suzuki [1,*] and Sergiy G. Gychka [2]

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[2] Department of Pathological Anatomy N2, Bogomolets National Medical University, 01601 Kiev, Ukraine; gychka59@gmail.com
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Abstract: The world is suffering from the coronavirus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). SARS-CoV-2 uses its spike protein to enter the host cells. Vaccines that introduce the spike protein into our body to elicit virus-neutralizing antibodies are currently being developed. In this article, we note that human host cells sensitively respond to the spike protein to elicit cell signaling. Thus, it is important to be aware that the spike protein produced by the new COVID-19 vaccines may also affect the host cells. We should monitor the long-term consequences of these vaccines carefully, especially when they are administered to otherwise healthy individuals. Further investigations on the effects of the SARS-CoV-2 spike protein on human cells and appropriate experimental animal models are warranted.

Keywords: cell signaling; coronavirus; COVID-19; SARS-CoV-2; spike protein; vaccine

Citation: Suzuki, Y.J.; Gychka, S.G. SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Host Cells: Implications for Possible Consequences of COVID-19 Vaccines. *Vaccines* **2021**, *9*, 36. https://doi.org/10.3390/vaccines9010036

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1. Introduction

The world is suffering from the coronavirus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a positive-sense, single-stranded RNA virus [1,2]. As of the end of December 2020, over 80 million people have been infected with SARS-CoV-2, causing 1.8 million deaths worldwide. SARS-CoV-2 uses its viral membrane fusion protein, known as a spike protein, to bind to angiotensin converting enzyme 2 (ACE2) as a 'receptor' in order to enter human host cells [3,4], causing severe pneumonia and acute respiratory distress syndrome (ARDS) [5]. Elderly patients with cardiovascular disease are particularly susceptible to developing serious COVID-19 conditions that in some cases lead to death, while young and healthy individuals are largely resistant to developing severe symptoms [1,6,7]. As COVID-19 continues to cause serious health, economic, and sociological problems, the world awaits the widespread rollout of effective vaccines that may end this pandemic.

The SARS-CoV-2 spike protein, a class I viral fusion protein, is critical to initiating the interactions between the virus and the host cell surface receptor, facilitating viral entry into the host cell by assisting in the fusion of the viral and host cell membranes. This protein consists of two subunits: Subunit 1 (S1) that contains the ACE2 receptor-binding domain (RBD) and Subunit 2 (S2) that plays a role in the fusion process [3,4] (Figure 1). The SARS-CoV-2 spike protein is the major target for the development of COVID-19 vaccines.

EXHIBIT
1-3

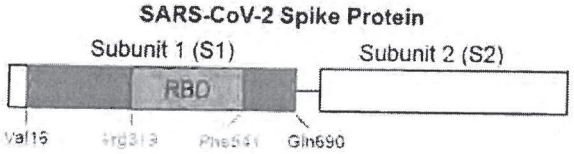

Figure 1. Structure of SARS-CoV-2 spike protein. The spike protein consists of Subunit 1 (S1) and Subunit 2 (S2). The S1 subunit contains the receptor-binding domain (RBD) that binds to ACE2 of the host cell membrane. The S2 subunit is responsible for fusion. In our previous study described in Sections 3 and 5, we used full-length S1 (Val16-Gln690) depicted with blue and red regions and the RBD only-containing protein (Arg319-Phe541) shown in red of the SARS-CoV-2 spike protein (GenBank Accession Number: QHD43416.1).

2. Development of Spike Protein-Based COVID-19 Vaccines

The remarkably rapid development of vaccines and therapeutics for COVID-19 in 2020 has been due to effective collaborations between governments and the private sector. On 9 November 2020, Pfizer and BioNTech announced that their mRNA-based vaccine candidate, BNT162b2, is more than 90% effective against COVID-19 [8]. This was welcome news in that it revealed that effective vaccines may soon become available. BNT162b2 encodes the SARS-CoV-2 spike protein to elicit virus-neutralizing antibodies [9,10]. More specifically, it encodes the full-length spike protein of SARS-CoV-2 with two amino acids mutated to proline in the S2 subunit to maintain the prefusion conformation, while its sister vaccine BNT162b1 (also from Pfizer/BioNTech) encodes only the RBD of the SARS-CoV-2 spike protein, trimerized by the addition of a T4 fibritin foldon domain [9–11]. Clinical trials have demonstrated that neither BNT162b1 [11] nor BNT162b12 [9,10] exhibit serious short-term adverse effects. On 10 December 2020, the results of a large clinical trial for BNT162b were published, showing that this vaccine conferred 95% protection in persons 16 years of age or older [12]. Long-term consequences of these vaccines are, however, unknown.

Another promising vaccine, mRNA-1273 by Moderna, is also an RNA vaccine that encodes the full-length SARS-CoV-2 spike protein [13]. Viral vector-based vaccines such as AZD1222 by AstraZeneca, which uses a non-replicating chimpanzee adenovirus vector [14], Ad26.COV2.S by Johnson & Johnson, a non-replicating adenovirus 26-based system [15], and Gam-COVID-Vac (Sputnik V) by Gamaleya Research Institute of Epidemiology and Microbiology [16], all express the SARS-CoV-2 spike protein. NVX-CoV2373 (Novavax), a recombinant protein-based vaccine [17], is also the full-length SARS-CoV-2 spike protein. These vaccines as well as many others under development [18–20] introduce the SARS-CoV-2 spike protein into our body, so that the production of antibodies and immunity against SARS-CoV-2 are stimulated.

3. SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Cells

It was found that the treatment of cultured primary human pulmonary artery smooth muscle cells (SMCs) or human pulmonary artery endothelial cells with the recombinant SARS-CoV-2 spike protein S1 subunit is sufficient to promote cell signaling without the rest of the viral components [21]. Furthermore, our analysis of the postmortem lung tissues of patients who died of COVID-19 has determined that these patients exhibited pulmonary vascular wall thickening, a hallmark of pulmonary arterial hypertension (PAH) [21]. Based on these results, we proposed that the SARS-CoV-2 spike protein (without the rest of the viral components) triggers cell signaling events that may promote pulmonary vascular remodeling and PAH as well as possibly other cardiovascular complications [21,22].

In our cell culture experiments, two recombinant SARS-CoV-2 spike proteins, both of which contain the RBD, were studied [21]. The full-length S1 subunit protein contains most of the S1 subunit (Val16–Gln690), while the RBD S1 subunit protein only contains the RBD region (Arg319–Phe541), as shown in Figure 1. Cultured primary human pulmonary artery SMCs and human pulmonary artery endothelial cells were treated with these proteins for 10 min. We found, using the phospho-specific MEK antibody, that the recombinant

full-length S1 subunit of SARS-CoV-2 alone at a concentration as low as 130 pM activated MEK, the activator of extracellular signal-regulated kinase (ERK) and a well-known signal transduction mechanism for cell growth [23]. By contrast, such activation of cell signaling by the spike protein did not occur in rat pulmonary artery SMCs [21].

While ACE2 is now well known as a 'receptor' to which the SARS-CoV-2 spike protein binds on human host cells in order to facilitate the membrane fusion and gain viral entry, the usual physiological function of ACE2 is not to serve as a membrane receptor to transduce intracellular signals. ACE2 is a type I integral membrane protein that functions as a carboxypeptidase, cleaving angiotensin II to angiotensin (1–7) and regulating blood pressure [24,25] (Figure 2). However, ten years ago, Chen et al. [26] reported the intriguing findings showing that ACE2 acts as a membrane receptor for cell signal transduction in response to the spike protein of SARS-CoV (now also known as SARS-CoV-1, the virus that caused the SARS outbreak in 2002–2004) in the human lung alveolar epithelial cell line, A549. The spike protein of SARS-CoV-1 is 76–78% identical to that of SARS-CoV-2 [27]. In their study, it was shown that the binding of the full-length spike protein to ACE2 triggered the casein kinase II-dependent activation of activator protein-1 (AP-1) transcription factor and subsequent gene transcriptional events [26]. Their finding on SARS-CoV-1 [26] and ours on SARS-CoV-2 [21] indicate that the spike protein remarkably functionally converts ACE2 (that is normally a peptidase enzyme) into a membrane receptor for cell signaling that uses the spike protein as a ligand for its activation (Figure 2).

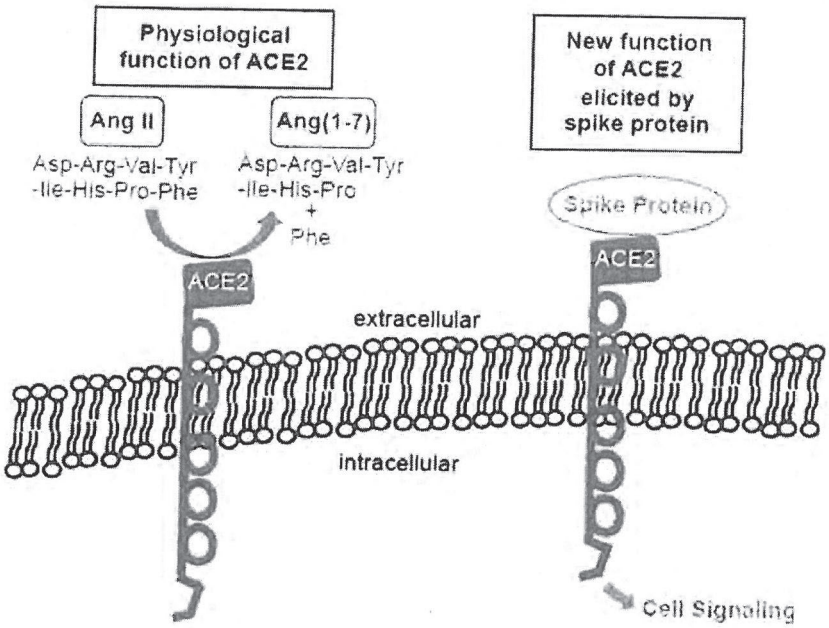

Figure 2. Biological functions of ACE2. In physiological situations, ACE2 functions as a carboxypeptidase enzyme that catalyzes the hydrolysis of angiotensin II (Ang II) into Ang(1–7) by cleaving off a phenylalanine (Phe). In the presence of the spike protein, this enzyme becomes a membrane receptor for cell signaling that uses the spike protein as a ligand for its activation.

Kuba et al. [28] showed that the injection of mice with recombinant SARS-CoV-1 spike protein reduced the ACE2 expression and worsened the acid-induced lung injury. In mice with an acid-induced lung injury, the recombinant SARS-CoV-1 spike protein dramatically increased angiotensin II, and the angiotensin receptor inhibitor losartan attenuated the spike protein-induced enhancement of lung injury [28]. Thus, these in vivo studies demonstrated that the spike protein of SARS-CoV-1 (without the rest of the virus) reduces the ACE2 expression, increases the level of angiotensin II, and exacerbates the lung injury.

The SARS-CoV-2 spike protein without the rest of the viral components has also been shown to activate cell signaling by Patra et al. [29]. The authors reported that the full-length SARS-CoV-2 spike protein expressed by the means of transient transfection, either in the human lung alveolar epithelial cell line A549 or in the human liver epithelial cell line Huh7.5, activated NF-κB and AP-1 transcription factors as well as p38 and ERK mitogen-activated protein kinases, releasing interleukin-6. This cell signaling cascade was found to be triggered by the SARS-CoV-2 spike protein downregulating the ACE2 protein expression, subsequently activating the angiotensin II type 1 receptor [29]. These experiments using transient transfection may reflect the intracellular effects of the spike protein that could be triggered by the RNA- and viral vector-based vaccines.

These results collectively reinforce the idea that human cells are sensitively affected by the extracellular and/or intracellular spike proteins though the activation of cell signal transduction.

4. Pulmonary Hypertension

PAH is a serious disease without a cure that can affect males and females of any age including children. The increased pulmonary vascular resistance in PAH results in right heart failure and subsequently death. Patients diagnosed with PAH only live for 2–3 years from the time of diagnosis on average if untreated [30,31]. Even with currently available therapies, only 60–70% of PAH patients survive for three years [32–35]. PAH is hard to detect because its symptoms (e.g., shortness of breath, fatigue, and dizziness) are similar to those of other common non-life threatening conditions, and the official diagnosis for PAH must be made through invasive right heart catheterization [36]. Endothelial dysfunction is a common feature of patients with PAH and COVID-19 [37,38].

PAH "outbreaks" have occurred in association with exposure to certain drugs or toxins [39]. A major outbreak of PAH occurred in 1965 and was associated with aminorex, a weight-loss stimulating drug [39,40]. Approximately 0.2% of people who took this drug developed PAH [40]. An epidemic was observed two years after the introduction of aminorex, and half of the patients died 10 years after the epidemic [39].

We studied pulmonary vessels of COVID-19 patients and those of H1N1 influenza-infected patients who died of ARDS [21]. The pulmonary arteries of postmortem COVID-19 patient lungs consistently exhibited histological characteristics of vascular wall thickening, mainly due to the hypertrophy of the tunica media. Detailed pathological analysis revealed that the boundaries between the vessels and the surrounding lung parenchyma have lost clarity, the SMCs of the middle lining of the arteries have enlarged, the nuclei of SMCs have swollen, and vacuoles have been generated in the cytoplasm of SMCs [21]. A morphometric analysis determined that the median pulmonary vascular wall thickness values were 15.4 μm for the COVID-19 patients and 6.7 μm for the influenza patients, and these values were significantly different from each other [21]. Pulmonary vascular wall thickening in COVID-19 patients was also observed on the computed tomography scan of the chest [41,42]. Thus, these results together indicated that COVID-19 is associated with pulmonary vascular wall thickening. Investigations on whether this pulmonary vascular wall thickening is related to clinically significant PAH and the role of the spike protein in the pathogenesis of PAH are warranted.

5. RBD Only-Containing SARS-CoV-2 Spike Protein Does Not Elicit Cell Signaling in Human Cells

In contrast to the full-length spike protein [26,29] or the full-length SARS-CoV-2 spike protein S1 subunit [21], we found that the RBD only-containing protein (Figure 1) did not promote cell signaling. Our Western blotting results monitoring the MEK activation showed that the mean ± SEM phosphorylated MEK to MEK protein ratio values were 0.05 ± 0.003 (untreated), 1.9 ± 0.07 (treated with the full-length S1 protein), and 0.05 ± 0.003 (treated with the RBD only-containing protein) for human pulmonary artery SMCs; and 0.09 ± 0.006 (untreated), 0.90 ± 0.06 (treated with the full-length S1 protein), and 0.10 ± 0.003 (treated with the RBD only-containing protein) for human pulmonary artery endothelial cells [21].

The different effects of the full-length S1 and RBD only-containing proteins may be important considering that BNT162b2 and many other COVID-19 vaccines express the full-length spike protein, while the BNT162b1 vaccine encodes only the RBD region [9–20]. There are some other RBD-based COVID-19 vaccines being developed as well [43]. It is possible that the RBD-based vaccines are less immunogenic, but may not affect the host cells. Thus, they may be less risky considering potential long-term adverse effects. However, in the in vivo study of the SARS-CoV-1 spike protein described above [28], a deletion mutant that only contained the RBD also worsened the acid-induced lung failure, like the full-length spike protein. Thus, further work is needed to understand effects of the full-length spike protein and the RBD-only containing protein in various biological processes.

6. Discussion

It is generally thought that the sole function of viral membrane fusion proteins is to allow the viruses to bind to the host cells for the purpose of viral entry into the cells, so that the genetic materials can be released and the viral replication and amplification can take place. However, recent observations suggest that the SARS-CoV-2 spike protein can by itself trigger cell signaling that can lead to various biological processes. It is reasonable to assume that such events, in some cases, result in the pathogenesis of certain diseases.

Our laboratory only tested the effects of the SARS-CoV-2 spike protein in lung vascular cells and those implicated in the development of PAH. However, this protein may also affect the cells of systemic and coronary vasculatures, eliciting other cardiovascular diseases such as coronary artery disease, systemic hypertension, and stroke. In addition to cardiovascular cells, other cells that express ACE2 have the potential to be affected by the SARS-CoV-2 spike protein, which may cause adverse pathological events. Thus, it is important to consider the possibility that the SARS-CoV-2 spike protein produced by the new COVID-19 vaccines triggers cell signaling events that promote PAH, other cardiovascular complications, and/or complications in other tissues/organs in certain individuals (Figure 3). We will need to monitor carefully the long-term consequences of COVID-19 vaccines that introduce the spike protein into the human body. Furthermore, while human data on the possible long-term consequences of spike protein-based COVID-19 vaccines will not be available soon, it is imperative that appropriate experimental animal models are employed as soon as possible to ensure that the SARS-CoV-2 spike protein does not elicit any signs of the pathogenesis of PAH or any other chronic pathological conditions.

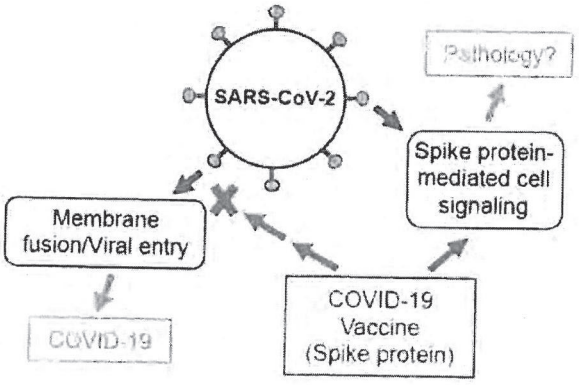

Figure 3. Possible actions of the SARS-CoV-2 spike protein. The SARS-CoV-2 spike protein of the intact virus targets ACE2 of the host cells to facilitate the membrane fusion and the viral entry. The SARS-CoV-2 spike protein also elicits cell signaling in human cells [21,29]. COVID-19 vaccines introduce the spike protein into the human body. In addition to eliciting an immune response that suppresses the viral entry, the spike protein produced by the COVID-19 vaccines may also affect the host cells, possibly triggering adverse events. Further investigations addressing this possibility are warranted.

7. Conclusions

In conclusion, the recent advancement in the SARS-CoV-2 spike protein-based COVID-19 vaccine development is exciting and has shed light on how to end the current pandemic. These vaccines should benefit elderly people with underlying conditions if they do not exhibit any acute adverse events. However, we need to consider their long-term consequences carefully, especially when they are administered to otherwise healthy individuals as well as young adults and children. In addition to evaluating data that will become available from SARS-CoV-2 infected individuals as well as those who received the spike protein-based vaccines, further investigations of the effects of the SARS-CoV-2 spike protein in human cells and appropriate animal models are warranted.

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[redacted]

CONSENT AND IMMUNIZATION RECORD FOR CORONAVIRUS DISEASE 2019 (COVID-19) VACCINE

Last Name _____ First Name _____ M. Initial _____

Date of Birth _____ Phone No. _____ Gender: M F

Mailing Address _____ City _____ State ____ Zip _____

For [redacted] *Employees Only:*

Employee ID _____ Social Security X X X – X X - _____ _____ _____ _____

Job Title _____ Dept. _____ Campus _____

Work Email _____ Work Phone No. _____

This vaccine is an investigational medicine to vaccinate individuals against COVID-19. This vaccine is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using this vaccine.

There may be risks and side-effects involved with taking this vaccine, both known and unknown. These may be a minor inconvenience such as fever or may be so severe as to cause death. Receiving this vaccine is voluntary and you can refuse to receive this vaccine now or at any point. It is unknown how effective this vaccine is if you have previously been infected with COVID-19. Immunocompromised individuals receiving this vaccine may have a diminished response to the vaccine.

For required reporting purposes, if you do not have a [redacted] electronic medical record, one will be created on your behalf.

I (we) understand that this vaccine is not recommended for those with a history of severe allergic reaction (e.g., anaphylaxis such as difficulty breathing; wheezing; swelling of the face, throat or tongue; sensation of airway closing; stridor; etc.) to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) or any components of the vaccine. The components of the vaccine are further described in the FDA Fact Sheet for Recipients and Caregivers.

Females Only: (_____) I (we) understand there is currently limited data available on the use of this vaccine in pregnant women, women who plan to become pregnant, or women who are breastfeeding. I (we) understand these risks are unknown and a conversation with my health care provider can further inform my decision to receive this vaccine.

I (we) knowingly and voluntarily release and agree to hold harmless [redacted], this facility, provider(s), and all of the [redacted] affiliates' and its officers, directors, agents and employees, from and against any and all liability of every kind arising from, related to, or in connection with my decision to receive this vaccine.

I (we) have had the opportunity to ask questions and I understand the benefit and risk of this vaccine. I (we) certify this form has been fully explained to me, that I (we) have read it or have had it read to me, that the blank spaces have been filled in, and that I (we) understand its contents.

I (we) voluntarily consent to receive the vaccine at this time and affirm that I (we) do not have any known allergies to this vaccine. I (we) understand that I must receive the second dose of the vaccine (if required) from the same manufacturer listed below during the appropriate time-frame established by the manufacturer. I (we) have been provided an opportunity to read, been provided a copy, and/or declined a copy of the FDA Fact Sheet for Recipients/Caregivers.

DATE: _____ TIME: _____ A.M. / P.M.

PATIENT/OTHER LEGALLY RESPONSIBLE PERSON:

_____ _____

Signature Print Name

For Vaccine Team Only:			
Vaccine Manufacturer	☐ Pfizer/BioNTech ☐ Moderna	**Date/time**	
Dose/Lot number		**Location (clinic/facility)**	
Expiration Date		**Administered by**	
FDA Fact Sheet Edition		**Dose/site**	

Scan to doc type: **Consent – Immunization**

EXHIBIT
1 - 4

[redacted]

CONSENT AND IMMUNIZATION RECORD FOR CORONAVIRUS DISEASE 2019 (COVID-19) VACCINE

VACCINES INVITED ARTICLE

Stanley A. Plotkin, Section Editor

Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997–2013

Pedro L. Moro, Jorge Arana, Maria Cano, Paige Lewis, and Tom T. Shimabukuro

Immunization Safety Office, Centers for Disease Control and Prevention, Atlanta, Georgia

Background. Vaccines are among the safest medical products in use today. Hundreds of millions of vaccinations are administered in the United States each year. Serious adverse reactions are uncommon. However, temporally associated deaths can occur following vaccination. Our aim was to characterize main causes of death among reports submitted to the US Vaccine Adverse Event Reporting System (VAERS), a spontaneous vaccine safety surveillance system.

Methods. We searched VAERS for US reports of death after any vaccination from 1 July 1997 through 31 December 2013. Available medical records, autopsy reports, and death certificates were reviewed to identify cause of death.

Results. VAERS received 2149 death reports, most (n = 1469 [68.4%]) in children. Median age was 0.5 years (range, 0–100 years); males accounted for 1226 (57%) reports. The total annual number of death reports generally decreased during the latter part of the study period. Most common causes of death among 1244 child reports with available death certificates/autopsy reports included sudden infant death syndrome (n = 544 [44%]), asphyxia (n = 74 [6.0%]), septicemia (n = 61 [4.9%]), and pneumonia (n = 57 [4.6%]). Among 526 adult reports, most common causes of death included diseases of the circulatory (n = 247 [46.9%]) and respiratory systems (n = 77 [14.6%]), certain infections and parasitic diseases (n = 62 [11.8%]), and malignant neoplasms (n = 20 [3.8%]). For child death reports, 79.4% received >1 vaccine on the same day. Inactivated influenza vaccine given alone was most commonly associated with death reports in adults (51.4%).

Conclusions. No concerning pattern was noted among death reports submitted to VAERS during 1997–2013. The main causes of death were consistent with the most common causes of death in the US population.

Keywords. death; vaccines; epidemiology; surveillance; vaccine safety.

When a death occurs shortly following vaccination, it is important to assess whether it was related to vaccination. In 2009–2010, a close temporal association between receipt of the pandemic influenza A(H1N1) vaccine (pH1N1) and 107 deaths (among 15 million doses of vaccine distributed in Japan) resulted in concern about a possible causal relationship, despite a lack of compelling epidemiologic or clinical evidence [1, 2]. Deaths following vaccination have had a negative impact on vaccination programs [3, 4], particularly in low- and middle-income countries implementing large-scale infant vaccination programs [5], even when investigations do not find evidence of a causal relationship.

In a review of reports of death following vaccination submitted to the Vaccine Adverse Event Reporting System (VAERS) from the early 1990s, the Institute of Medicine concluded that most were coincidental, not causally associated [6]. A separate review of 1266 death reports to VAERS from 1990 to 1997 found that almost half were attributable to sudden infant death syndrome (SIDS), which decreased in frequency following recommendations in the early 1990s to change infant sleep environment (ie, sleep on back or side) [7]. As new vaccines are added to the childhood vaccination schedule and use of existing vaccines expands, such as

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the universal recommendation in 2010 for influenza vaccination for all persons aged ≥6 months [8, 9], it is important to continue to monitor death reports to VAERS. We reviewed reports of death after vaccination reported to VAERS from 1997 through 2013.

METHODS

Vaccine Adverse Events Reporting System

VAERS is a US national vaccine safety surveillance system, co-administered by the Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration, that receives spontaneous reports of adverse events following vaccination [10]. VAERS accepts reports from vaccine manufacturers, healthcare providers, vaccine recipients, and others. The VAERS report form collects information on age, sex, vaccines administered, the AE experienced, and health history. Signs and symptoms of adverse events are coded by trained personnel using the Medical Dictionary for Regulatory Activities (MedDRA), a clinically validated, internationally standardized terminology [11]. Each VAERS report may be assigned 1 or more MedDRA preferred terms. A report is considered serious based on the Code of Federal Regulations definition if 1 or more of the following is reported: death, life-threatening illness, hospitalization or prolongation of existing hospitalization, or permanent disability [12]. For nonmanufacturer serious reports, medical records are routinely requested and made available to VAERS personnel. For death reports, efforts are made to obtain autopsy reports and death certificates that contain information on the cause of death.

We analyzed VAERS death reports received by 1 June 2014 for individuals vaccinated with any vaccine from 1 July 1997 through 31 December 2013. Non-US and duplicate death reports were excluded. Hearsay reports (secondhand reports) with no vaccination date recorded were also excluded.

Clinical Review of Death Reports

CDC physicians reviewed the VAERS reports, available autopsy findings, death certificates, and medical records to assess causes of death. Cause of death was classified into major *International Classification of Diseases, Tenth Revision* (*ICD-10*) diagnostic categories, which have been described previously [13]. We did not attempt to assess death reports for causal relationships with vaccination, although we did review specific causes of death where causal relationships between vaccination and death have been established or a plausible theoretical risk exists; these included anaphylaxis, intussusception, Guillain–Barré syndrome (GBS), yellow fever vaccine–associated viscerotropic disease, smallpox complications leading to death, and syncope after vaccination leading to head trauma and subsequent death [14].

We calculated descriptive statistics for sex, age groups, onset interval (time from vaccination to death), year of vaccination, cause of death, and vaccines administered. Calculations were performed using SAS software, version 9.2 (SAS Institute, Cary, North Carolina). Because VAERS is a routine surveillance program that does not meet the definition of research, it is not subject to institutional review board review and informed consent requirements.

RESULTS

We identified 2149 death reports in VAERS (Table 1). Most reports involved children aged 0–17 years and males. Autopsy reports and/or death certificates were available for 1770 (82.4%) reports. The median onset interval, the period from vaccination to death, was 3 days (range, 0–2442 days) for all ages, 2 days (range, 0–1478 days) for infants (<1 year of age), 5 days (range, 0–2442 days) for children 1–17 years, and 3 days (range, 0–2011 days) for adults (≥18 years). Among the 1469 reports in children aged 0–17 years, 1166 (79.4%) received >1 vaccine on the day of vaccination; among infants (n = 1165), 1004 (86.2%) received >1 vaccine. Among the 666 reports for adults aged ≥18 years, 92 (13.8%) received >1 vaccine on the day of vaccination.

Table 1. Death Reports in the Vaccine Adverse Event Reporting System Among Persons Vaccinated 1 July 1997–31 December 2013

Characteristic	No. (%)
Total reports	2149
Child reports (0–17 y)	1469 (68.4)
Adult reports (≥18 y)	666 (30.9)
Unknown age	14 (0.7)
Age, mo, median (range)	6 (0–1204)
Age group, y[a]	
<1	1165 (54.2)
1–4	197 (9.2)
5–9	30 (1.4)
10–17	77 (3.6)
18–45	139 (6.5)
46–64	152 (7.1)
≥65	375 (17.5)
Male sex[b]	1226 (57.0)
Onset, d, median (range), all reports[c]	3 (0–2442)
Onset, d, median (range), infants (<1 y)	2 (0–1478)
Type of reporter[d] (n = 2090)	
Vaccine provider	982 (47.1)
Other	672 (32.2)
Manufacturer	288 (13.8)
Parent/patient	144 (6.9)
With autopsy report and/or death certificate	1770 (82.4)

[a] Age unknown for 14 reports.
[b] Sex unknown for 21 reports.
[c] Onset unknown for 170 reports.
[d] Type of reporter unknown for 63 reports.

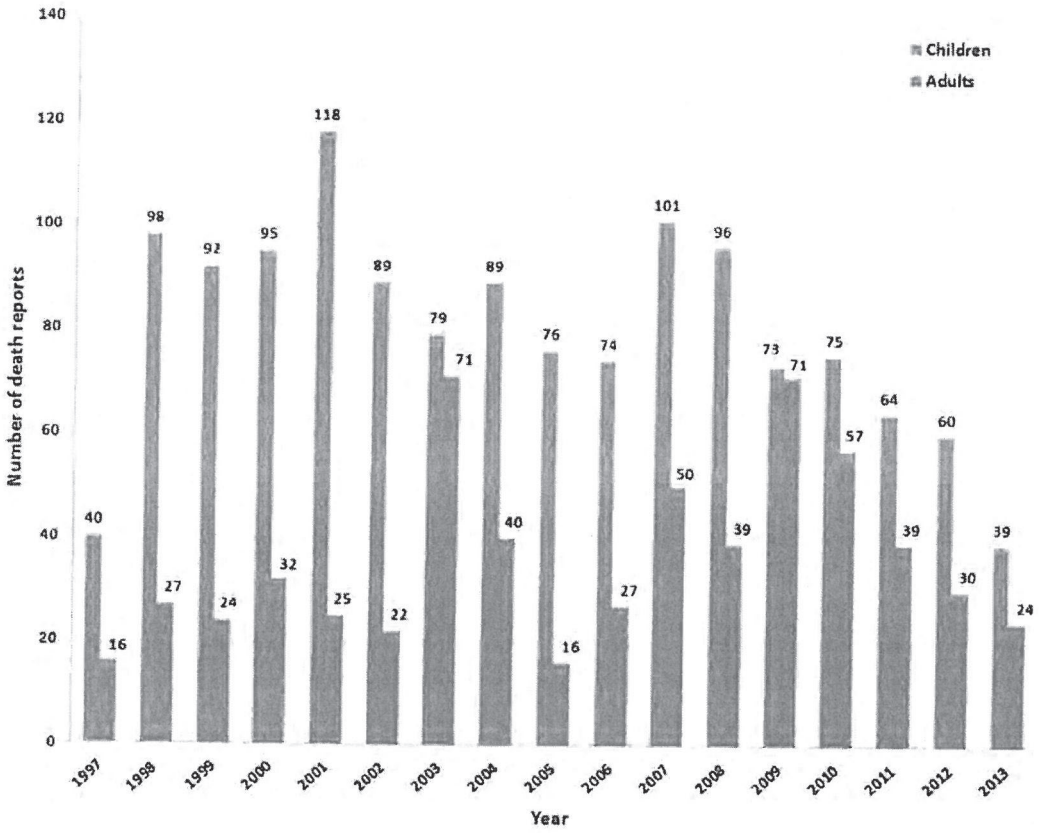

Figure 1. Trends in death reports in children (0–17 years old) and adults (≥18 years old) in the Vaccine Adverse Event Reporting System, 1 July 1997–31 December 2013.

The number of death reports in children exceeded those in adults in all years, and in both groups the number of reports has decreased in recent years (Figure 1).

Reports of Children

Causes of Death

Among reports of death in children with autopsy findings and/or death certificates available for review, the most common causes of death by *ICD-10* major group (Table 2) included SIDS and diseases of the respiratory system, with pneumonia as the most common cause of death in the respiratory category. "Injury, poisoning and certain other consequences of external causes" were noted in 96 reports, with asphyxiation being the most common cause of death in this category. Septicemia or sepsis was the fourth most common cause of death. In 146 of 1244 (11.7%) reports, the autopsy report or death certificate stated the cause of death was undetermined. SIDS reports progressively decreased in frequency from a peak in 1998 (n = 50) to a nadir in 2011 (n = 21). Most SIDS cases were among infants 2–4 months of age (n = 398 [66%]) and mostly among males (n = 375 [62.2%]) (Table 3). SIDS reports were most common among children who had received DTaP-HepB-IPV (diphtheria and tetanus toxoids and acellular pertussis adsorbed, hepatitis B, and inactivated poliovirus vaccine) plus *Haemophilus influenzae* type b (Hib) plus 7- or 13-valent pneumococcal conjugate vaccine (PCV7 or PCV13) (11.6%) followed by HepB vaccine given alone (9%).

Vaccines Administered

The most common vaccines and vaccine combinations associated with child death reports for all years combined are listed in Table 4. For child death reports, 79.4% received >1 vaccine on the same day. The most common vaccines in children were DTaP-HepB-IPV + Hib + PCV7 or PCV13 (n = 127 [8.7%]) followed by HepB vaccine given alone (n = 115 [7.8%]).

Among children aged 0–17 years, DTaP vaccine was most common among death reports from 1998 through 2002 (Figure 2). From 2003 through 2009, PCV7 became the predominant vaccine seen in death reports, and in 2011 and 2012, PCV13 was the predominant vaccine. PCV7 was licensed and recommended

Table 2. Most Common Causes of Death Among Reports in Persons Aged 0–17 Years (n = 1244) in the Vaccine Adverse Event Reporting System, 1 July 1997–31 December 2013

ICD-10 Major Group	No. (%)
Symptoms, signs, and abnormal clinical and laboratory findings, not elsewhere classified	703 (56.5)
Sudden infant death syndrome	544
Undetermined	146
Diseases of the respiratory system	98 (7.9)
Pneumonia	57
Injury, poisoning, and certain other consequences of external causes	96 (7.7)
Asphyxiation	74
Certain infections and parasitic diseases	80 (6.4)
Septicemia, sepsis	61
Diseases of the nervous system	73 (5.9)
Meningitis	18
Seizures	18
Diseases of the circulatory system	69 (5.5)
Other forms of heart disease	54
Congenital malformations, deformations, chromosomal abnormalities	39 (3.1)
Diseases of the digestive system	25 (2.0)
External causes of morbidity	16 (1.3)
Assault	11
Other causes of death	45 (3.6)

Abbreviation: *ICD-10*, *International Classification of Diseases, Tenth Revision*.

Table 3. Characteristics of Sudden Infant Death Syndrome Reports in the Vaccine Adverse Event Reporting System, 1997–2013

Characteristic	No. (%)
SIDS reports	603 (28.1)
Male sex[a]	375 (62.2)
Onset, d, median (range)	3 (0–121)
Age, mo, median (range)	2 (0–37)
Type of reporter[b] (n = 581)	
Provider	340 (58.5)
Other	171 (29.4)
Parent/patient	37 (6.4)
Manufacturer	33 (5.7)
Age group, mo (n = 603)	
<12	582 (96.5)
12–48	20 (3.3)
Unknown	1 (0.2)
No. of SIDS reports with autopsy reports and/or death certificate	544 (90.2)
Top 4 vaccines given individually or simultaneously	
DTaP-HepB-IPV + Hib + PCV7 or PCV13	70 (11.6)
HepB	54 (8.9)
DTaP + Hib-HepB + IPV + PCV7 or PCV13	52 (8.6)
DTaP + Hep B + Hib + IPV	47 (7.8)
DTaP + Hib + IPV + PCV7 or PCV13	42 (6.9)

Total death reports = 2149.

Abbreviations: DTaP, diphtheria, tetanus, and acellular pertussis vaccine; DTaP-IPV-Hib, combination diphtheria, tetanus, and acellular pertussis, inactivated poliovirus, and *Haemophilus influenzae* type b conjugate vaccine; HepB, hepatitis B vaccine; Hib, *Haemophilus influenzae* type b conjugate vaccine; Hib-HepB, combination *Haemophilus influenzae* type b conjugate and hepatitis B vaccine; IPV, inactivated poliovirus vaccine; PCV7, 7-valent pneumococcal conjugate vaccine; PCV13, 13-valent pneumococcal conjugate vaccine; SIDS, sudden infant death syndrome.

[a] Sex unknown in 2 reports.

[b] Type of reporter unknown for 22 reports.

for use in 2000, and the first reports of death following PCV7 vaccination were reported that year (n = 20). The rotavirus pentavalent vaccine (RV5) was licensed for use in 2006, and the first reports of death following RV5 occurred that year.

Reports of Adults

Causes of Death

Among reports of death in adults with autopsy or death certificate findings (Table 5), the most common causes of death included diseases of the circulatory system, diseases of the respiratory system, and certain infections and parasitic diseases; the most common causes of death in each of these categories included ischemic heart disease, pneumonia, and septicemia or sepsis, respectively. In 16 of 526 (3%) reports, the cause of death was undetermined.

Vaccines Administered

Among adult reports, the most commonly associated vaccines (Table 4) included IIV3 (n = 342 [51.4%]), herpes zoster (shingles) vaccine (n = 41 [6.2%]), 23-valent pneumococcal polysaccharide vaccine (n = 39 [5.9%]), and 2009 pH1N1 inactivated monovalent vaccine (n = 37 [5.6%]), all of which were given alone. Of reports of death among adults, trivalent inactivated influenza vaccine (IIV3) was the most commonly received vaccine for all years, with the exception of 2009 when the 2009 pH1N1 monovalent inactivated vaccine was the most commonly received vaccine and IIV3 was the second most common.

Prespecified Conditions as a Cause of Death

Anaphylaxis was identified as the cause of death in 6 reports; 5 after IIV3 vaccine. The onset interval for all 5 reports was <24 hours. In one report, the patient received IIV3 and ceftriaxone concomitantly. Intussusception was the stated cause of death in 6 reports; all involved administration of several vaccines simultaneously; in 5 reports patients received a rotavirus vaccine. The median onset interval was 5 days (range, 4–16 days) for these 5 reports. Two reports had an onset interval >6 days.

GBS was reported as the cause of death or a contributor to the death, or listed as a diagnosis, in 23 reports; vaccines administered

Table 4. Five Most Common Vaccines and Vaccine Combinations (Simultaneous Administration) for Child and Adult Death Reports in the Vaccine Adverse Event Reporting System, 1 July 1997–31 December 2013

Type of Report	No. (%)
Child reports (n = 1469)	
DTaP-HepB-IPV + Hib + PCV7 or PCV13	127 (8.7)
HepB	115 (7.8)
DTaP + Hib-HepB + IPV + PCV7 or PCV13	102 (7.0)
DTaP-HepB-IPV + Hib + PCV7 or PCV13 + RV5	84 (5.7)
DTaP + Hep B + Hib + IPV	77 (5.2)
Adult reports (n = 666)	
IIV3	342 (51.4)
Herpes zoster	41 (6.2)
PPSV23	39 (5.9)
Influenza A(H1N1) (pandemic) inactivated	37 (5.6)
IIV3 + PPSV23	15 (2.3)

Abbreviations: DTaP, diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed; DTaP-HepB-IPV, diphtheria and tetanus toxoids and acellular pertussis adsorbed, hepatitis B, and inactivated poliovirus vaccine; HepB, hepatitis B vaccine; Hib, *Haemophilus influenzae* type b conjugate vaccine; Hib-HepB, *Haemophilus influenzae* type b conjugate and hepatitis B vaccine; IIV3, trivalent inactivated influenza vaccine; IPV, inactivated poliovirus vaccine; PCV7, 7-valent pneumococcal conjugate vaccine; PCV13, 13-valent pneumococcal conjugate vaccine; PPSV23, 23-valent pneumococcal polysaccharide vaccine; RV5, rotavirus vaccine (pentavalent).

included only IIV3 in 20 reports and three reports where IIV3 was given in combination with pneumococcal vaccine, 2009 pH1N1 inactivated monovalent vaccine, or HepB/varicella zoster vaccine. The median onset interval for these 23 reports was 12 days (range, 2–44 days). In 19 of 23 reports, the GBS was verified as cause of death by review of medical records. There was one report of syncope after vaccination leading to head trauma and resulting in death; details about this case have been reported previously [15]. Two reports involved deaths resulting from possible complications of smallpox vaccine. One report involved a 26-year-old male active-duty soldier who died suddenly after smallpox and IIV3 vaccination. The cause of death was eosinophilic myocarditis (hypersensitivity myocarditis) compatible with postvaccinial myocarditis. A second death report involved a 18-year-old male active-duty soldier who received anthrax, smallpox, and typhoid fever vaccines and died 2 weeks later. The cause of death was "complications from smallpox vaccination." Autopsy findings included myocarditis with dilated cardiopathy and pulmonary edema. Yellow fever vaccine viscerotropic disease was the stated cause of death in one report involving a 22-year-old woman who received yellow fever vaccine 7 days before death.

DISCUSSION

This comprehensive review of death reports to VAERS for the period 1 July 1997 through 31 December 2013 indicates that the most common causes of death in VAERS were consistent with the leading causes of death in the US population (Table 6) [13]. The 2149 deaths described in this study were reported to VAERS during a period of time when approximately 2 billion doses of vaccine were distributed for use in the United States. This translates to roughly 1 reported death per 1 million doses of vaccine distributed. Because the majority of death reports were in children, the most common causes of death were in this age group. SIDS was the leading cause of death (28.1%) among all reports and accounted for 51.7% of death reports in infants, which is consistent with infant mortality data that place SIDS as the third leading cause of death in the United States among infants, after congenital malformations, deformations, and chromosomal abnormalities; and disorders related to short gestation and low birthweight [13, 16]. The male predominance of death reports in our study is driven by SIDS reports in which males accounted for 62%. This is consistent with studies that found males to be at higher risk of SIDS [17]. SIDS occurs rarely during the first month of life and peaks between 2–3 months of age [17]. Because SIDS peaks at a time when children are receiving many recommended vaccinations, it would not be unexpected to observe a coincidental close temporal relationship between vaccination and SIDS [18]. SIDS deaths in the United States have been declining since the early 1990s for a variety of factors that include recommended changes in sleeping position and environment, clarification of the case definition, and diagnostic coding shifts [19–22]. This downward trend in SIDS reports has also been observed in SIDS reports submitted to VAERS since the early 1990s [7] and has continued during the years of this review from 1997 through 2013. There is considerable evidence that vaccination is not causally associated with SIDS [18, 22, 23], including an Institute of Medicine (IOM) review in 2003 that rejected a causal association between the whole cell pertussis–containing vaccine (which is no longer in use in the United States) and SIDS and between exposure to multiple simultaneous vaccines and SIDS [21].

Other leading causes of death among VAERS reports included diseases of the circulatory system and diseases of the respiratory system. Diseases of the circulatory system, the most common causes of death among VAERS death reports in adults, are the leading causes of death in the US population. Some other leading causes of death among VAERS reports included pneumonia and septicemia/sepsis, both of which rank among the top 11 leading causes of death in the US population [13].

In different age groups, the most common vaccines temporally associated with deaths tended to be those typically recommended and given at the particular age (Table 4). Thus, for child reports, the most common vaccines were combination vaccines given simultaneously with other vaccines (ie, DTaP-HepB-IPV, Hib, PCV7 or PCV13). An exception was the first dose of HepB vaccine, generally given during the first month

Figure 2. Trends in death reports by vaccine type in children aged 0–17 years, Vaccine Adverse Event Reporting System, 1 July 1997–31 December 2013. Only the most common vaccines associated with death reports are shown. Vaccines shown may be given alone or with other vaccines and may be single or combined antigen vaccines, so percentages of death reports in any given year may exceed 100%. Abbreviations: DTaP, diphtheria, tetanus, and acellular pertussis vaccine; DTaP-HepB-IPV, combination diphtheria, tetanus, and acellular pertussis, hepatitis B, and inactivated poliovirus vaccine; DTaP-IPV-Hib, combination diphtheria, tetanus, and acellular pertussis, inactivated poliovirus and *Haemophilus influenzae* type b conjugate vaccine; HepB, hepatitis B vaccine; Hib, *Haemophilus influenzae* type b conjugate vaccine; IPV, inactivated poliovirus vaccine; PCV7, 7-valent pneumococcal conjugate vaccine; PCV13, 13-valent pneumococcal conjugate vaccine; RV5, rotavirus vaccine (pentavalent).

of life. HepB vaccine was the second most common vaccine associated with death reports. A previous study investigated neonatal death reports submitted to VAERS after HepB vaccine during 1991 through 1998 and did not find any safety pattern of concern [24], and a population-based study did not find a significant difference in the proportion of HepB-vaccinated (31%) and -unvaccinated (35%) neonates dying of unexpected causes [25].

We noted that death reports appear to follow the Weber effect [26], a tendency for new medical products or products perceived to be new to have higher reporting rates for adverse events initially, which then decline despite steadily increasing prescribing rates. For example, the peak in number of death reports during 2001 appears to coincide with an increase in PCV7 use following its licensure and recommendation for use in 2000. RV5 was licensed and recommended in 2006, and the peak in the number of death reports after RV5 occurred in 2008. DTaP-HepB-IPV was first licensed and recommended in 2002 and the first death reports in VAERS were observed in 2003 with the highest number of reports in 2007, which was followed by a decline in subsequent years.

VAERS strengths include its broad national scope and timeliness, and its use for detecting signals of potential vaccine safety problems that may be further studied in other epidemiologic studies. However, any finding in VAERS needs to be interpreted with caution given the inherent limitations of passive surveillance systems, such as over- or underreporting, biased reporting, and inconsistency in quality and completeness of reports [10]. VAERS generally cannot assess if a vaccine caused an adverse event. VAERS does not collect data on the number of individuals vaccinated; therefore, with no denominator data, it is not possible to calculate rates of adverse events. Likewise, VAERS does not collect data on the total number of vaccinated individuals who died; therefore, it is not possible to calculate death rates following vaccination.

Because a large number of vaccines are given to young children (often simultaneously) at scheduled well-child visits, especially during the first year of life, deaths occurring in close

Table 5. Most Common Causes of Death Among Reports in Persons Aged ≥18 Years (n = 526) in the Vaccine Adverse Event Reporting System, 1 July 1997–31 December 2013

ICD-10 Major Group	No. (%)
Diseases of the circulatory system[a]	247 (46.9)
Ischemic heart disease	119
Other forms of heart disease	74
Cerebrovascular diseases	15
Hypertensive diseases	16
Diseases of the respiratory system	77 (14.6)
Pneumonia	34
Chronic lower respiratory diseases	20
Other diseases of the respiratory system	13
Certain infections and parasitic diseases	62 (11.8)
Septicemia, sepsis	48
Diseases of the nervous system	43 (8.2)
Malignant neoplasms	20 (3.8)
Injury, poisoning, and certain other consequences of external causes	20 (3.8)
Other causes of death	57 (10.8)

Abbreviation: *ICD-10*, *International Classification of Diseases, Tenth Revision*.

[a] Pulmonary heart disease and diseases of pulmonary circulation (n = 12), diseases of arteries, arterioles, and capillaries (n = 7), diseases of veins, lymphatic vessels, and lymph nodes, not elsewhere classified (n = 3).

Table 6. Age-Adjusted Mortality Rates for the 15 Leading Causes of Death in the United States, 2010[a]

Cause of Death	Age-Adjusted Death Rate (per 100 000 US Standard Population)
All causes	747.0
1. Diseases of heart (heart disease)	179.1
2. Malignant neoplasms (cancer)	172.8
3. Chronic lower respiratory diseases	42.2
4. Cerebrovascular diseases (stroke)	39.1
5. Accidents (unintentional injuries)	38.0
6. Alzheimer's disease	25.1
7. Diabetes mellitus (diabetes)	20.8
8. Nephritis, nephrotic syndrome, and nephrosis (kidney disease)	15.3
9. Influenza and pneumonia	15.1
10. Intentional self-harm (suicide)	12.1
11. Septicemia	10.6
12. Chronic liver disease and cirrhosis	9.4
13. Essential hypertension and hypertensive renal disease (hypertension)	8.0
14. Parkinson's disease	6.8
15. Pneumonitis due to solids and liquids	5.1

Source: Murphy et al [16].

temporal association following vaccination are likely to occur by chance alone. It is important for immunization programs to be aware of background rates of adverse events, including mortality rates in the population, to develop risk communication strategies to help communities understand deaths following vaccination, which can be disruptive to vaccination programs [27]. For example, Hib vaccine has been introduced progressively into some Asian countries' immunization programs as a component of a combination pentavalent vaccine replacing diphtheria–whole-cell pertussis (DTwP) or DTwP-HepB. During introduction of these vaccines into Sri Lanka, India, and Vietnam in 2008–2010, deaths were reported among a small number of vaccine recipients, prompting authorities to suspend the use of these vaccines [5]. More recently, 4 deaths among elderly individuals who received the IIV3 vaccine in Italy prompted the Italian Medicines Agency to temporarily suspend the use of that vaccine in that country [28]. Investigations into the causes of death in all these examples found that the vaccines were not implicated. Other examples of how deaths following vaccinations can be disruptive to immunization programs and public health have been discussed in the scientific literature [27].

Few epidemiologic studies have investigated the occurrence of deaths following vaccination or assessed mortality rates in vaccinated and unvaccinated populations. A previous review of death reports in VAERS during 1990–1997 [7] did not identify any pattern of concern. The findings in our review are consistent with previous findings, especially related to SIDS reports. A study using electronic health record databases in the Vaccine Safety Datalink (VSD) between 2005 and 2008 estimated the mortality rate among vaccinated individuals and also assessed major causes of death [29]. The age-adjusted death rate within 60 days of vaccination was 442.5 deaths per 100 000 person-years, which is lower than the US death rate during 2008 reported by the National Center for Health Statistics of 758.3 per 100 000 population [29]. The authors attributed the lower death rate in the VSD vaccinated population to a "healthy vaccinee effect," meaning that people are more likely to receive a vaccine when they are relatively healthy and free of disease. The leading causes of death in the VSD vaccinated population were similar to those reported by the National Center for Health Statistics for the general US population.

In our VAERS review, we did not detect any concerning patterns that would suggest causal relationships between vaccination and deaths. With rare exceptions (eg, anaphylaxis), the evidence from multiple VAERS reviews in combination with findings from IOM reviews and a VSD study using electronic health record databases do not suggest a causal relationship or increased risk of death following vaccination. Continuous monitoring and assessment of death reports in VAERS is warranted to ensure public confidence in the immunization program. Risk assessment and communication strategies should be in place to rapidly respond to reports of deaths following vaccination.

Notes

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Disclaimer. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the US Food and Drug Administration.

Potential conflicts of interest. All authors: No potential conflicts of interest.

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